DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–371]

RIN 1218–AB46

Occupational Exposure to Tuberculosis

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The Occupational Safety and Health Administration is proposing a health standard, to be promulgated under section 6(b) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 655, to control occupational exposure to tuberculosis (TB). TB is a communicable, potentially lethal disease that afflicts the most vulnerable members of our society: the poor, the sick, the aged, and the homeless. As many as 13 million U.S. adults are presently believed to be infected with TB; over time, more than 1 million of these individuals may develop active TB disease and transmit the infection to others. TB remains a major health problem with 22,813 active cases reported in the U.S. in 1995. 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 multidrug-resistant strains of *Mycobacterium tuberculosis,* which are often fatal. Although it is the responsibility of the U.S. Public Health Service to address the problem of tuberculosis in the general U.S. population, OSHA is solely responsible for protecting the health of workers exposed to TB as a result of their job.

OSHA estimates that more than 5 million U.S. workers are exposed to TB in the course of their work: in hospitals, homeless shelters, nursing homes, and other work settings. 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. The risk confronting these workers as a result of their contact with TB-infected individuals may be as high as 10 times the risk to the general population. Although the number of reported cases of active TB has slowly begun to decline after a resurgence between 1985–1992, 16 states reported an increase in the number of TB cases in 1995, compared with 1994. Based on a review of the data, OSHA has preliminarily concluded that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings are at significant risk of incurring TB infection while caring for their patients and clients or performing certain procedures. To reduce this occupational risk, OSHA is proposing a standard that would require employers to protect TB-exposed employees by means of infection prevention and control measures that have been demonstrated to be highly effective in reducing or eliminating job-related TB infections. These measures include the use of respirators when performing certain high hazard procedures on infectious individuals, procedures for the early identification and treatment of TB infection, isolation of individuals with infectious TB in rooms designed to protect those in the vicinity of the room from contact with the microorganisms causing TB, and medical follow-up for occupationally exposed workers who become infected. OSHA has preliminarily determined that the engineering, work practice, and administrative controls, respiratory protection, training, medical surveillance, and other provisions of the proposed standard are technologically and economically feasible for facilities in all affected industries.

DATES: Written comments on the proposed standard must be postmarked on or before December 16, 1997 and notices of intention to appear at the informal rulemaking hearings must be postmarked on or before December 16, 1997.

Parties requesting more than 10 minutes for their presentation at the hearings and parties submitting documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than December 31, 1997.

The informal public hearings will begin at 10:00 a.m. on the first day of hearing and at 9:00 a.m. on each succeeding day. The informal public hearings will be held in Washington, D.C. and are scheduled to begin on February 3, 1998.

ADDRESSES: Hearings will be held in the Auditorium of the U.S. Department of Labor (Frances Perkins Building), 200 Constitution Avenue, NW, Washington, D.C. Subsequent additional informal public hearings will be held in other U.S. locations. A **Federal Register** notice will be issued upon determination of the locations and dates of these hearings.

Comments on the proposed standard, Notices of Intention to Appear at the informal public hearings, testimony, and documentary evidence are to be submitted in quadruplicate to the Docket Officer, Docket No. H–371, Room N–2625, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, telephone (202) 219–7894. Comments of 10 pages or fewer may be transmitted by fax to (202) 219–5046, provided the original and three copies are sent to the Docket Officer thereafter. The hours of operation of the Docket Office are 10:00 a.m. until 4:00 p.m.

Written comments, Notices of Intention to Appear at the informal rulemaking hearings, testimony, documentary evidence for the hearings, and all other material related to the development of this proposed standard will be available for inspection and copying in the Docket Office, Room N–2625, at the above address.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N–3647, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, Telephone (202) 219–8148, FAX (202) 219–5986.

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References to the rulemaking record are in the text of the preamble. References are given as ''Ex.'' followed by a number to designate the reference in the docket. For example, ''Ex. 1'' means exhibit 1 in the Docket H–371. This document is a copy of the petition for a permanent standard filed by the Labor Coalition to Fight TB in the Workplace on August 25, 1993. A list of the exhibits and copies of the exhibits are available in the OSHA Docket Office.

I. Introduction

The preamble to the Proposed Standard for Occupational Exposure to Tuberculosis discusses the events leading to the development of the proposed standard, the health effects of exposure to tuberculosis, and the degree and significance of the risk. An analysis of the technological and economic feasibility of the proposal and an explanation of the rationale supporting the specific provisions of the proposed standard are also included.

Public comment on all matters discussed in this notice and all other relevant issues is requested for the purpose of assisting OSHA in the development of a new standard for occupational exposure to tuberculosis.

A. Issues

OSHA requests comment on all relevant issues discussed in this preamble, including the health effects, risk assessment, significance of risk determination, technological and economic feasibility and requirements that should be included in the final standard. OSHA is especially interested in responses, supported by evidence and reasons, to the following questions. This list is provided to assist persons in formulating comments, but is not intended to be all inclusive or to indicate that participants need to respond to all issues or follow this format. Please give reasons for your answers and provide data when available.

Specific issues of concern to OSHA are the following:

Health Effects

1. What, if any, additional studies or case reports on TB should be included in the health effects analysis?

2. Is there information that will provide data for estimating the rise in Multidrug-resistant TB (MDR–TB)? Is the rise in MDR–TB a serious threat?

Risk Assessment

1. Are there alternative risk assessment methodologies available? What are they? Are there other studies available that would be useful for assessing risk?

2. Are there factors other than or in addition to the ones OSHA has chosen that would be useful in estimating the background risk for TB?

Technological and Economic Feasibility

1. Are OSHA's estimates of the numbers and types of workers currently exposed to *M. tuberculosis* reasonable? If not, please provide estimates of the number of workers currently at risk and the percentage of the total workforce these workers represent, by industry.

2. Are OSHA's estimates of controlled access rates (i.e., the percentage of workers currently at risk who would remain at risk after employers minimize the number of workers exposed to individuals with suspected or confirmed infectious TB) reasonable? If the number of workers exposed to individuals with suspected or confirmed infectious TB is minimized, by what percentage could the number of workers at risk be reduced in each affected industry? In each industry, what are the job categories that would continue to be occupationally exposed?

3. Are OSHA's estimates of the numbers of affected establishments reasonable? If not, please provide estimates of the number of affected establishments, by industry.

4. Are OSHA's estimates of occupational and job turnover rates reasonable? If not, please provide estimates of turnover rates for each of the affected industries.

5. Under what conditions would social work, social welfare services, teaching, law enforcement or legal services need to be provided to individuals identified as having suspected or confirmed infectious TB? What, if any, procedures could not be postponed until such individuals are determined to be noninfectious? How many workers in each of these categories may need to have contact with individuals with suspected or confirmed infectious TB under these conditions?

6. Using the proposed definition of ''suspected infectious TB,'' how many individuals with suspected infectious TB are likely to be encountered for every confirmed infectious TB case in each of the covered industries?

7. Are OSHA's estimates of the average number of suspected or confirmed infectious TB cases that would be transferred, per establishment in each industry, reasonable? If not, on average, how many TB cases per facility in each of the affected industries would be transferred?

8. How are individuals with suspected infectious TB transferred to establishments with AFB isolation facilities? Who pays for the transport of such cases, particularly for individuals transferred from homeless shelters? OSHA solicits comment on the feasibility of temporary AFB isolation facilities in homeless shelters and on methods that could be used to temporarily isolate individuals with suspected or confirmed infectious TB in homeless shelters.

9. Of the suspected infectious TB cases referred to hospitals from other facilities, how many are immediately ruled out without needing to be isolated?

10. Are OSHA's estimates of the number of necessary AFB isolation rooms reasonable? Are existing AFB isolation rooms reasonably accessible to facilities that transfer individuals with suspected or confirmed infectious TB?

11. What types of respirators are currently being used to protect workers against occupational exposure to *M. tuberculosis*?

12. Which of the NIOSH-approved N95 respirators meet all of the proposed criteria, including fit testing and fit checking criteria?

13. Are OSHA's estimates of respirator usage rates reasonable? For each of the covered industries, how often could respirators meeting the proposed requirements be reused and still maintain proper working condition? How often, on average, would respirators need to be replaced? Please specify the type of respirator.

14. OSHA has assumed, in its Preliminary Economic Analysis, that hospitals will have licensed health care professionals on-site to perform the medical procedures that would be required by the proposed rule, and that in the other industries, employees will have to travel off-site to receive the medical procedures. Which of the other affected industries typically have licensed health care professionals on site who could perform the required medical procedures? If employers were allowed two weeks to provide the medical procedures, rather than being required to provide them prior to initial assignment to jobs with occupational exposure, will it be less likely that employees will have to travel off site to receive these tests/procedures? What would the costs be if employees travel off-site for these tests/procedures?

15. Are OSHA's estimates of baseline compliance reasonable? If not, what types of controls are currently in place to protect workers against occupational exposure to *M. tuberculosis*, and what proportion of facilities in each of the affected industries currently are using such controls?

16. For facilities that have implemented controls to protect workers against occupational exposure to *M. tuberculosis*, how effective have such controls been in reducing the transmission of TB?

17. OSHA's Initial Regulatory Flexibility Analysis assesses the impacts of the proposed standard on small entities using the Small Business Administration's (SBA) size standards.

In addition, OSHA analyzed the impacts of the proposed standard on entities employing fewer than 20 workers. Are these definitions appropriate for the covered industries? If not, how should small entities be defined for each industry?

18. The SBA defines small government jurisdictions as ''governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000.'' OSHA requests comment on the number of such small government jurisdictions.

19. Some parties have suggested that OSHA should allow the use of the CDC guidelines as an alternative to the proposed rule. However, OSHA believes that the CDC guidelines are not written in a regulatory format that would allow OSHA's Compliance Safety and Health Officers (CSHOs) to determine whether or not an employer is in compliance with the Guidelines. Others have suggested that OSHA could judge compliance with the guidelines by determining the number or rate of skin test conversions at the employer's facility. OSHA does not believe that smaller facilities have an adequate population for trends in test conversions to have any statistical validity. OSHA welcomes suggestions on any methods of making the CDC guidelines an enforceable alternative to an OSHA regulation or methods of measuring performance that could be applied across all types and sizes of facilities.

20. Because of the limited availability of data, OSHA characterized the risk in many sectors as similar to that in hospitals, and less than that documented in nursing homes and home health care. OSHA welcomes industry-specific data on test conversion rates or active case rates.

21. OSHA is unable to determine the effectiveness of specific elements of an effective infection control program in hospitals. OSHA welcomes any evidence on the relative effectiveness of individual elements in such programs, such as the identification and isolation of suspect cases, the use of engineering controls, the use of respirators, and employee training.

22. OSHA based its estimate of the effectiveness of infection control programs in other sectors on studies of the effectiveness of such programs in hospitals. OSHA welcomes any data concerning the effectiveness of OSHA's proposed infection prevention measures, or of other alternative infection control measures, in sectors other than hospitals.

23. SBREFA Panel members suggested a number of alternative approaches to the regulation. OSHA believes that it has at least partially adopted a number of these approaches. OSHA welcomes comments and suggestions on these approaches and the extent to which OSHA should further adopt them:

- Cooperative initiatives, such as expanding OSHA's current cooperative initiative with JCAHO;
- A federal-state government public health partnership to develop guidelines in various industry sectors;
- Performance standards developed with the assistance of federal, state, and local government, and labor and industry stakeholders;
- Separate approaches for the health and non-health industries (the approach for the health industries could be keyed to existing industry standards and that for non-health industries to guidelines);
- Different levels of compliance requirements for different industries, depending on their expertise, resources, and risk;
- Less stringent trigger mechanisms for the more burdensome portions of the standard; and
- Separate standards for each affected industry.

24. OSHA is proposing to include homeless shelters in the Scope of the standard. During the informal public hearings, OSHA intends to schedule a special session for participants to present additional information on homeless shelters. Also, OSHA is conducting a special study of the homeless shelter sector. The information gathered in the study will be placed in the docket for public comment. OSHA welcomes comment on any of the topics this study will cover including:

- Percentage of homeless persons that would meet OSHA's definition of a suspected infectious TB case (A breakdown of which symptoms are particularly common will help OSHA construct the best definition);
- Turnover among the homeless who use shelters;
- Employee turnover in homeless shelters;
- Trends in the 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 TB hazards so that baseline compliance with the proposed standard can be determined. Of particular concern to OSHA are:

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

- Feasibility of hospitals providing 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; and
—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; and
- The OSH Act applies to employees, not bona fide volunteers. However, OSHA understands that some states may, as a matter of law, require facilities to provide volunteers with protections established by OSHA standards. OSHA is seeking information on:

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

25. In what states, if any, do employers provide volunteers in the sectors affected by this proposed standard with the same protections as they provide to employees? How many volunteers might be affected by such requirements?

26. OSHA is concerned that medical removal protection and medical treatment of active cases of TB may have significant economic impacts on small firms that have an employee with an active case of TB. Is there any form of insurance available for covering the costs of medical removal protection or medical treatments required by the OSHA standard? Should OSHA consider phasing-in these provisions of the standard?

27. OSHA believes that substance abuse treatment centers, particularly in-patient treatment centers, normally have entry procedures that may include medical examinations. OSHA solicits comments on entry procedures for substance abuse treatment programs, the extent to which these entry procedures now include medical examinations, and the extent to which these examinations now include and examination for TB symptoms.

28. OSHA requests comment on the effects of extended compliance phase-in dates for the proposed requirements,

particularly for respirators, for small businesses and facilities relying on charitable and/or Medicare and Medicaid funding.

29. OSHA requests comment on all assumptions and estimates used in developing the Preliminary Economic Analysis. Please provide reasons and data to support suggested changes to the assumptions and estimates.

30. The World Health Organization (WHO) has launched an initiative to reduce active TB through the use of multi-drug therapy and using directly observed therapy. OSHA solicits comment on whether it should revise its risk assessment or any of its benefits estimates as a result of this initiative.

31. OSHA requests comment on the number of affected facilities that are tribally-operated, by industry.

General

1. A number of provisions in the proposed standard are triggered by the identification of an individual as having either ''suspected infectious tuberculosis'' or ''confirmed infectious tuberculosis.'' Of these provisions, are there some that should be triggered only once an individual has been identified as having ''confirmed infectious tuberculosis?'' If so, which provisions and why?

2. A number of the proposed standard's provisions require compliance or performance on an annual basis, e.g., reviews of the exposure control plan, the biosafety manual for laboratories, and the respiratory protection program; certification of biological safety cabinets; fit testing or a determination of the need for fit testing of respirators; medical histories, TB skin tests; and training. In addition, certain requirements must be performed on a semi-annual basis, e.g., inspection and performance monitoring of engineering controls, verification of air flow direction in laboratories, and, in some instances, TB skin testing. How can OSHA reduce the aggregate burden of these requirements, particularly in small entities, while still providing equal protection to employees? Of these annual and semi-annual provisions, which, if any, should be performed less frequently? Why and at what frequency? Which of these provisions, if any, should be performed more frequently? Why and at what frequency?

Scope

1. Is there information demonstrating risk of TB transmission for employees in work settings other than those included in the scope? Should OSHA, for example, expand the scope of this standard to cover all or some offices of general practitioners or dentists and if so, how? Should OSHA expand the scope to cover all teachers?

2. Are there provisions of the standard with which emergency medical services, home health care, and home-based hospice care employers cannot comply because their employees are at temporary work settings over which the employer has little or no control? If so, what are those provisions and why would an employer be unable to comply with them?

3. In covering only long-term care facilities for the elderly, is OSHA excluding similar facilities where there is increased risk of transmission of TB? If so, what are these facilities? Should OSHA include long-term care populations in addition to the elderly, such as long-term psychiatric care facilities? If so, what are these populations?

4. OSHA is proposing that employers provide medical management and follow-up for their employees who work in covered work settings, but who are not occupationally exposed, when they have an exposure incident resulting from an engineering control failure or similar workplace exposure. Is this the best way of assuring such employees receive medical management and follow-up?

5. OSHA is covering employees who have occupational exposure in covered work settings yet are not employees of the work setting (e.g., physician employed by another employer with hospital privileges, who is caring for a TB patient in the hospital). Can this be made more clear?

6. OSHA has proposed that facilities offering treatment for drug abuse be covered in the scope of the standard. Is coverage of such facilities appropriate? What factors unique to facilities that offer treatment for drug abuse would make compliance with the provisions of this proposed standard infeasible (e.g., would complying with certain provisions of the standard compromise the provision of services at facilities that offer treatment for drug abuse)?

Application

1. OSHA has proposed that an employer covered under the standard (other than an operator of a laboratory) may claim reduced responsibilities if he or she can demonstrate 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 had no 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 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. Are there alternative methods that can be used to assure protection of employees in areas where infectious TB has not recently been encountered?

Exposure Control Plan

1. OSHA has proposed that the employer's exposure control plan contain certain policies and procedures. What, if any, policies and procedures should be added to the plan?

2. The proposed standard requires exposure incidents and skin conversions to be investigated, but does not require aggregate data regarding employee conversions to be collected and analyzed. Would the collection and analysis of aggregate data provide benefits beyond those provided by investigating each individual exposure incident or conversion? Why or why not? If aggregate data collection and analysis were required, what type of analysis should be required, at what analytical endpoint should employer action be required, and what should that action be?

3. OSHA has set forth the extent of responsibility for transfer of individuals based upon the type of work setting where such individuals are encountered. What are current practices regarding transfer of individuals with suspected or confirmed infectious TB in the work settings covered by the proposal?

Work Practices and Engineering Controls

1. Is OSHA's time limit of 5 hours following identification for transferring an individual with suspected or confirmed infectious TB to another facility or placing the individual into AFB isolation appropriate? If not, what is the maximum amount of time that an individual should be permitted to await transfer or isolation in a facility before the employer must implement the other provisions of the proposed standard?

2. OSHA has considered requiring facilities that encounter 6 or more individuals with confirmed infectious TB within the past 12 months to provide engineering controls in intake areas where early identification procedures are performed (e.g., emergency departments, admitting areas). Should this be a requirement? Are there types of controls, engineering or otherwise, that would be effective in controlling transmission in intake areas? Would the trigger of 6 individuals with confirmed infectious TB be appropriate?

3. Are there methods other than smoke trail testing and continuous monitors that would be effective for verifying negative pressure in AFB isolation rooms or areas?

4. OSHA is requiring engineering controls to be inspected and performance monitored every 6 months. Is this frequency appropriate?

5. OSHA is allowing exhaust air from AFB isolation rooms or areas where *M. tuberculosis* may be aerosolized that cannot feasibly be discharged directly outside to be HEPA-filtered and recirculated back into general ventilation. Is permitting such recirculation appropriate? If used, should there be any requirements to detect system failure?

6. OSHA is permitting stand-alone HEPA filter units to be used as a primary control measure. Is this appropriate? What, if any, methods other than ventilation and filtration can provide consistent protection?

7. Should ambulances that have carried an individual with suspected or confirmed infectious TB be required to be ventilated for a specific period of time or in a particular way before allowing employees to enter without a respirator? What engineering controls are available for ambulances?

Laboratories

1. The standard does not require labeling of laboratory specimens. Should OSHA require that laboratory specimens be labeled within the facility or when specimens are being shipped? If so, what should the label contain? Are there other agencies that require these specimens be labeled? What are these agencies and what is required?

2. OSHA has attempted to incorporate the CDC/NIH recommendations given in ''Biosafety in Microbiological and Biomedical Laboratories'' into the standard. Do any provisions need to be added in order for employees in clinical and research laboratories to be fully protected against exposures to *M. tuberculosis*?

Respirators

1. OSHA is requiring employees who are transporting an unmasked individual with suspected or confirmed infectious TB within a facility to wear a respirator. Is this appropriate? How often would an individual with suspected or confirmed infectious TB be transported unmasked through a facility? Under what circumstances would it be infeasible to mask such an individual? What other precautions should be taken when transporting such an individual who is not masked?

2. OSHA is requiring that maintenance personnel use respiratory protection during maintenance of air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* When would it be necessary to access such an air system at the time it was carrying air that may contain aerosolized *M. tuberculosis*? Should OSHA require that such air systems be purged and shut down whenever these systems are accessed for maintenance or other procedures?

3. OSHA has received information that the use of certain kinds of respirators in helicopters providing emergency medical services may hamper pilot communication. Have other air ambulance services encountered this problem? Does this problem exist when the employee is using a type N95 respirator or other types of respiratory protection such as powered air purifying respirators? What other infection control or industrial hygiene practices could be implemented to minimize employee exposure in these circumstances?

4. The CDC states that there may be selected settings and circumstances (e.g., bronchoscopy on an individual with suspected or confirmed infectious TB or an autopsy on a deceased individual suspected of having had active TB at the time of death) where the risk of transmission may be such that increased respiratory protection such as that provided by a more protective negative-pressure respirator or a powered air purifying respirator may be necessary. Are there circumstances where OSHA should require use of a respirator that is more protective than a type N95 respirator? If so, what are the circumstances and what type of respiratory protection should be required?

5. OSHA is proposing that respirators be fit-tested annually, which is consistent with general industrial hygiene practice, or, in lieu of an annual fit test, that employees have their need to receive the annual fit test be evaluated by the physician or other licensed health care professional, as appropriate. For the circumstances and conditions regulated by this standard, will the evaluation provide enough ongoing information about the fit of a respirator to be an adequate substitute for fit testing? Should OSHA require that an actual fit test be performed periodically? If so, at what frequency?

6. OSHA has not included any provisions regarding the use of supplied air respirators. Are there circumstances in which supplied air respirators would be used to protect against *M. tuberculosis*? Should OSHA include provisions addressing supplied air respirators in the standard?

7. OSHA is permitting the reuse of disposable respirators provided the respirator does not exhibit excessive resistance, physical damage, or any other condition that renders it unsuitable for use. Will the respirators continue to protect employees throughout the reuse period?

8. In the proposed standard for TB, OSHA has included separate provisions for all aspects of a respiratory protection program for tuberculosis. What other elements might need to be included? Which respiratory protection provisions, if any, are not appropriate for protection against TB? Please provide reasons and data to support inclusion or exclusion of particular provisions.

Medical Surveillance

1. Should any provisions be added to the Medical Surveillance program?

2. OSHA has not required that physical exams be included as part of the baseline evaluation. Is there information that is essential to medical surveillance for TB that can only be learned from a baseline physical exam?

3. OSHA is specifying tuberculin skin testing frequencies for employees with negative skin tests. Should tuberculin skin testing be administered more or less frequently? Are there other ways to determine the frequency of tuberculin skin testing?

4. OSHA is proposing that employees entering AFB isolation rooms or areas be skin tested every 6 months. However, employees providing home health care, home care, and home-based hospice care are to be skin tested annually. Employees entering the home of an individual who has suspected or confirmed infectious TB may have the same potential for exposure to aerosolized *M. tuberculosis* as employees who enter an isolation room. In light of this, should employees providing care to individuals with suspected or confirmed infectious TB in private homes be skin tested every 6 months?

5. OSHA is requiring that all tuberculin skin testing be administered, read, and interpreted by or under the supervision of a physician or other licensed health care professional, as appropriate, according to current CDC recommendations. Should OSHA require specific training for individuals who are administering, reading, and interpreting tuberculin skin tests? If so, what type of training should be required?

6. Should OSHA require a declination form for employees who do not wish to undergo tuberculin skin testing?

7. OSHA is including Medical Removal Protection (MRP) provisions for employees who are unable to wear respiratory protection or who contract infectious tuberculosis. Are there additional provisions that need to be included? What remedies are available to employees in states where worker compensation system do not consider occupational TB a compensable disease? What benefits are provided to workers who are unable to wear a respirator?

8. OSHA is requiring that employees who must wear a respirator be provided a face-to-face determination of their ability to wear the respirator. Does this determination need to be made through a medical evaluation or would the use of an appropriately designed questionnaire be adequate? What would be the advantages and disadvantages of relying on a questionnaire to make this determination? Are there sample questionnaires that have proven to be effective for determining an employee's ability to wear a respirator?

9. OSHA has drafted Medical Surveillance, paragraph (g), to explain first who must be provided with the protections listed in the paragraph and how the surveillance is to be administered and secondly, in paragraphs (g)(2), Explanation of Terms, and (g)(3), Application, how the general medical terms are to be construed to meet the standard and in what instances the medical examinations or tests are to be offered. The Agency realizes that there is some repetition in these paragraphs and seeks comment on whether there might be a better way to list the requirements.

Communication of Hazards and Training

1. OSHA is requiring that signs for isolation rooms and areas bear a ''STOP'' Sign and the legend ''No Admittance Without Wearing A Type N95 or More Protective Respirator.'' Is there another sign that would assure patient confidentiality while providing adequate notification of the hazard and the necessary steps to minimize the hazard for employees who may be inadvertently exposed?

2. OSHA is requiring that ducts be labeled ''Contaminated Air—Respiratory Protection Required.'' Should OSHA require that duct labels also include the ''STOP'' sign?

3. Is the labeling of ducts carrying air that may contain aerosolized *M. tuberculosis* (e.g., from isolation rooms and areas, labs) at all access points feasible? What, if any, equally protective alternative exists to permanent labeling in situations where an exhaust duct from a room may or may not be carrying air containing aerosolized *M. tuberculosis* (e.g., the exhaust duct would only be carrying aerosolized *M. tuberculosis* when an individual with infectious TB is being isolated in the room)?

Dates

1. OSHA has proposed that very small businesses with fewer than 20 employees be given an additional 3 months to comply with the standard's engineering control provisions (i.e., the start-up date for engineering controls for small businesses would be 270 days from the Effective Date of the standard). Are there other requirements of the proposed standard (e.g., respiratory protection) for which very small businesses should be given additional time to come into compliance? If so, for which provisions would they need additional time and why? Are 20 employees an appropriate cut-off for this purpose? Are there other employers that may need extended time to achieve compliance?

Definitions

1. A number of provisions in the standard are triggered by the identification of an individual as having ''suspected infectious tuberculosis.'' Under the definition of ''suspected infectious tuberculosis'', OSHA has proposed criteria that the Agency believes are the minimum indicators that, when satisfied by an individual, require an employer to consider that the individual may have infectious tuberculosis. Are there other criteria that should be included in this definition?

2. Coverage of an employee under the standard is based upon the definition of ''occupational exposure.'' Similar to OSHA's Bloodborne Pathogens standard, occupational exposure is dependent upon reasonable anticipation of contact with an individual with suspected or confirmed infectious tuberculosis or with air that may contain aerosolized *M. tuberculosis.* Are there additions that could be made to this definition that would help employers determine which of their employees are occupationally exposed?

3. OSHA has proposed requirements for research laboratories that differ from those of clinical laboratories. The standard includes definitions of ''research laboratory'' and ''clinical laboratory'' to assist the employer in differentiating between these two types of laboratory. Do the definitions clearly differentiate between these two types of laboratories? Should such a distinction be made? Are there any modifications that should be made to these definitions?

B. Information Collection Requirements

This proposed Tuberculosis standard contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA'95), 44 U.S.C. 3501 *et seq.* and the regulation at 5 CFR § 1320. PRA'95 defines collection of information to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.'' [44 U.S.C. § 3502(3)(A)].

The title, description of the need for and proposed use of the information, summary of the collections of information, description of the respondents, and frequency of response of the information collection are described below with an estimate of the annual cost and reporting burden, as required by 5 CFR § 1320.5(a)(1)(iv) and § 1320.8(d)(2). Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OSHA invites comments on whether the proposed collection of information:

(1) Ensures that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Estimates the projected burden accurately, including whether the methodology and assumptions used are valid;

(3) Enhances the quality, utility, and clarity of the information to be collected; and

(4) Minimizes the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Title: Tuberculosis 29 CFR 1910.1035.

Description: The proposed Tuberculosis (TB) Standard is an occupational safety and health standard that will prevent or minimize occupational exposure to TB. The standard's information collection requirements are essential components that will protect employees from occupational exposure. The information will be used by employers and employees to implement the protection

required by the standard. OSHA compliance officers will use some of the information in their enforcement of the standard.

Respondents: The respondents are employers whose employees may have occupational exposure in the following settings: hospitals; long-term care facilities for the elderly; correctional facilities and other facilities that house inmates or detainees; hospices; shelters for the homeless; facilities that offer treatment for drug abuse; facilities where high hazard procedures are performed; and laboratories that handle specimens that may contain *M. tuberculosis* or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of *M. tuberculosis.*

Also, occupational exposure occurring during the provision of social work, social welfare services, teaching, law enforcement or legal services would be covered if the services are provided in the work settings previously mentioned, or in residences, to individuals who are in AFB isolation or are segregated or otherwise confined due to having suspected or confirmed infectious TB. Respondents also include employers whose employees are occupationally exposed during the provision of emergency medical services, home health care and home-based hospice care. Approximately 101,875 employers will be responding to the standard.

Total Estimated Cost: First year $62,972,210; Recurring years $53,691,915.

SUMMARY OF THE COLLECTION OF INFORMATION

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Exposure Control Plan:				
(c)(2)(i)	101,875	All Affected Employers to Develop Plan.	• 24 hours per Hospital • 8 hours per Facility for all Other Industries	906,980
(c)(2)(vii)(B)	101,875	Annual Reviews and Updates for All Affected Employers.	• 8 hours per Hospital • 2 hours per Facility for all Other Industries	238,243
Respiratory Protection:				
(f)(2)	82,138	All Employers not Qualified for Appendix A Program to Develop Program.	• 8 hours per Hospital • 4 hours per Facility for all Other Industries	335,323
(f)(5), Appendix B	2,207,580	Initially, for all employees assigned respirators.	• 30 minutes per employee	551,962
	22,078	Annual refit tests for 1% of population assigned respirators.	• 30 minutes per employee	5,520
(f)(8)	82,138	Annual Evaluation of Program for All Affected Employers not Qualified for Appendix A Program.	• 2 hours per Hospital • 1 hour per Facility for all Other Industries	83,831
Medical Surveillance:				
• Medical History (g)(3)(i)(A)	1,831,724	Initially for All Affected Employees	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	1,831,724
	1,595,432	Annually for All Affected Employees in Facilities not Qualified for Appendix A.	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	1,595,432
	47,953	Initially, for New Employees	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	47,953
• Medical Examination (inc. History and Physical) (g)(3)(i)(B)–(D).	47,863	Annually, 3% of Controlled Population at Risk estimated to request exam as a result of having signs or symptoms of TB; have a TST conversion; or indicated as a result of an exposure incident.	• 2 hours per Hospital Employee in Facilities not Qualified for Appendix A (inc. LHCP time). • 1½ hour per Employee in All Other Industries (inc. travel time)	72,518
• Tuberculin Skin Tests				
Initial 2-Step TST (g)(3)(i)(A)	474,627	Initially, for Entire Controlled Population at Risk.	• 1½ hours per Hospital Employee (inc. LHCP time). • 2¼ hour per Employee in All Other Industries (inc. travel time)	1,026,377
Exposure Incident (g)(3)(i)(C).	8,268	Annually, 2% of Controlled Population at Risk in Facilities Qualified for Appendix A.	• 1½ hours per Hospital Employee (inc. LHCP time). • 2¼ hour per Employee in All Other Industries (inc. travel time)	17,879
Pre-Exit (g)(3)(i)(E)	76,257	Annually for Employment Turnover	• 1 hour for each Hospital Employee (inc. LHCP time). • 1½ hour per Employee in All Other Industries (inc. travel time)	110,504
Prior to Initial Assignment	76,257	All New Employees with Occupational Exposure.	• 1½ hour per Hospital Employee (inc. LHCP time).	165,756

SUMMARY OF THE COLLECTION OF INFORMATION—Continued

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Annual (g)(3)(ii)(A)	413,400	All employees in facilities not qualified for Appendix A.	• ½ hour per Hospital Employee (inc. LHCP time). • 45 minutes per Employee in all Other Industries (inc. travel time)	297,991
Additional 6-month TST (g)(3)(iii).	131,367	All employees who: • Enter an AFB isolation room or area • Perform or are present during the performance of high-hazard procedures • Transport or are present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle • Work in an intake area in facilities where 6 or more confirmed TB cases have been encountered in the past 12 mos	• 1 hour per Hospital Employee (inc. LHCP time). • 1½ hour for each Employee in All Other Industries (inc. travel time)	171,314
• Information Provided to Licenced Health Care Professional (LHCP) (g)(6)(I).	1,965,967	Information for each affected establishment to provide a copy of the rule, and for information on each employee with a respirator.	• 10 minutes per employee	327,661
	558,549	Information for each new employee assigned a respirator.	• 10 minutes per employee	93,091
	64,692	Information surrounding exposure incidents (2% of controlled population at risk).	• 10 minutes per employee	10,782
• LHCP Written Opinion (g)(7)	2,745,188	Initially, for each medical procedure performed.	• 5 minutes per written opinion	228,766
	2,034,269	Annually, for each medical procedure performed.	• 5 minutes per written opinion	169,522
Training:				
(h)(3)(ii)(B)	202,066	Number of training sessions in first year.	• 2 hours for employees required to wear respirators. • 1 hour for employees with occupational exposure who are not assigned respirators • Assumes 20 employees per session	237,829
(h)(3)(ii)(A)	106,258	Number of training sessions for new employees entering affected occupations for the first time + number of training sessions for employees staying in affected occupations, but starting new jobs.	• For new employees: 2 hours for employees required to wear respirators 1 hour for employees with occupational exposure who are not assigned respirators ½ hours for employees required to wear respirators 15 minutes for employees with occupational exposure who are not assigned respirators	50,193
(h)(3)(ii)(C)	154,966	Recurring number of training sessions.	• For 25% of exposed employees unable to demonstrate competence:. 1 hour for employees required to wear respirators ½ hour for employees with occupational exposure who are not assigned respirators • For 75% of exposed employees able to demonstrate competence • Assumes 20 employees per session	57,313
Recordkeeping:				
Medical (I)(1)(I)	3,713,645	Initially, to create a medical record for each affected employee.	• 10 minutes to set up each record	631,320
	1,358,800	Create medical records for each new employee with occupational exposure.	• 10 minutes to set up each record	230,996
	2,447,669	Annually, for each medical procedure performed.	• 5 minutes to update each record	195,814

SUMMARY OF THE COLLECTION OF INFORMATION—Continued

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Training (I)(3)(I)	264,451	Initially, to create records for each training session.	• 10 minutes to create each training record.	44,957
	217,351	Annually, to reflect recurring training sessions and initial training for new employees.	• 10 minutes to create each training record.	36,950
Engineering controls (I)(4)(I)	24,761	Annually, for each engineering control.	• 5 minutes per record	3,962
Availability (I)(5)	2,037	Annually, for 2% of affected employers.	• 5 minutes per employer	163
Transfer to NIOSH	1	Annually, for estimated 1 employer per year to transfer records.	• 1 hour per employer	1
Totals.				
• First-Year				7,098,011
• Recurring				3,655,728

[1] Estimates represent average burden hours per response. The actual burden hours per response will vary depending on factors such as the size of the facility, current practices at the facility, and whether the facility transfers or admits individuals with suspected or confirmed infectious TB.

Note: Estimates take into account baseline compliance with the proposed requirements.

The Agency has submitted a copy of the information collection request to OMB for its review and approval. Interested parties are requested to send comments regarding this information collection to the Office of Information and Regulatory Affairs, Attn. OSHA Desk Officer, OMB New Executive Office Building, 725 17th Street NW, Room 10235, Washington DC 20503.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the final information collection request: they will also become a matter of public record.

Copies of the referenced information collection request are available for inspection and copying in the OSHA Docket Office and will be mailed immediately to any person who request copies by telephoning Todd Owen at (202) 219–7075. For electronic copies of the Tuberculosis information collection request, contact the Labor News Bulletin Board (202) 219–4784, or OSHA web page on the Internet at http://www.osha.gov/. Copies of the information collection requests are also available at the OMB docket office.

C. Federalism

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Throughout the development of this proposed standard, OSHA has sought and received assistance from state representatives. Representatives of state departments of health and labor and industries have helped direct OSHA to pertinent information and studies on TB and have submitted drafts of state standards relevant to TB. In addition, representatives of state occupational safety and health departments participated in the review of the draft standard by OSHA field offices and in OSHA's TB Stakeholder meetings, where the requirements of the proposed standard were presented and information was collected from employers, employees, and their representatives on what was being done to prevent occupational exposure to TB in the various worksites and how an OSHA standard for TB could further reduce the exposures.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such State-Plan states must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

The proposed tuberculosis standard is drafted so that employees in every State will be protected by general, performance-oriented standards. To the extent that there are State or regional peculiarities, States with occupational safety and health plans approved under Section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this standard, of and by itself, allows for flexibility by States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

There is a clear national problem related to occupational safety and health for employees exposed to *M. tuberculosis*. Approximately 6.5% of the U.S. adult population is infected (i.e., carrying the tuberculosis bacillus, not manifesting active disease), and although the prevalence of TB infection and disease varies throughout the country, TB disease has been reported in every state. Political and geographic boundaries do not contain infection and disease spread. The U.S. population is mobile, moving freely from place to place for business and pleasure. Immigrants, a group whose members are known to have a high prevalence of TB, settle throughout the country. While there are counties that do not report cases in a given year, the counties change from year to year along with the number of cases reported. In addition, reports do not always reflect all the locations where exposure incidents can occur; infectious TB cases are often transferred from their site of diagnosis to a distant location for treatment and reported as a TB case only in the county

where treatment is administered. Finally, underreporting may occur because some individuals with infectious TB, in particular the homeless and clients of drug abuse facilities, do not avail themselves of further diagnosis and treatment. TB infection and disease is truly national in scope.

Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

D. State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months after the publication of a final standard for occupational exposure to tuberculosis or amend their existing standard if it is not ''at least as effective'' as the final Federal standard. OSHA anticipates that this standard will have a substantial impact on state and local employees. The states and territories with occupational safety and health state plans are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees). Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (''the Act'') is ''to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. § 651(b). To achieve this goal Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. §§ 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of Act's enactment), 655(b) (authorizing promulgation of standards pursuant to notice and comment), 654(b) (requiring employers to comply with OSHA standards).

A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' 29 U.S.C. § 652(8).

A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk, and is economically feasible, technologically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency actions, supported by substantial evidence, and is better able to effectuate the Act's purposes than any national consensus standard it supersedes. See 58 Fed. Reg. 16612—16616 (March 30, 1993).

OSHA has generally considered, at a minimum, a fatality risk of 1/1000 over a 45-year working lifetime to be a significant health risk. See the Benzene standard, *Industrial Union Dep't* v. *American Petroleum Institute*, 448 U.S. 607, 646 (1980); the Asbestos standard, *International Union, UAW* v. *Pendergrass*, 878 F.2d 389, 393 (D.C. Cir. 1989).

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. *American Textile Mfrs. Institute* v. *OSHA*, 452 U.S. 490, 513 (1981) (''*ATMI*''), *American Iron and Steel Institute* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991)(''*AISI*'').

A standard is economically feasible if industry can absorb or pass on the costs of compliance without threatening its long-term profitability or competitive structure. See *ATMI*, 452 U.S. at 530 n. 55; *AISI*, 939 F.2d at 980.

A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. *ATMI*, 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994) (''*LOTO III*'').

All standards must be highly protective. See 58 FR 16614—16615; *LOTO III*, 37 F.3d at 669. However, health standards must also meet the ''feasibility mandate'' of Section 6(b)(7) of the Act, 29 U.S.C. § 655(b)(5). Section 6(b)(5) requires OSHA to select ''the most protective standard consistent with feasibility'' that is needed to reduce significant risk when regulating health hazards. *ATMI*, 452 U.S. at 509.

Section 6(b)(5) also directs OSHA to base health standards on ''the best available evidence,'' including research, demonstrations, and experiments. 29 U.S.C. § 655(b)(5). OSHA shall consider ''in addition to the attainment of the highest degree of health and safety protection * * * the latest scientific data * * * feasibility and experience gained under this and other health and safety laws.'' *Id*.

Section 6(b)(7) authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. § 655(b)(7).

Finally, whenever practical, standards shall ''be expressed in terms of objective criteria and of the performance desired.'' *Id*.

III. Events Leading to the Proposed Standard

Tuberculosis (TB) is a contagious disease caused by the bacterium *Mycobacterium tuberculosis (M. tuberculosis)*. Infection is usually acquired by the inhalation of airborne particles carrying the bacterium. These airborne particles, called droplet nuclei, can be generated when persons with infectious pulmonary or laryngeal TB cough, sneeze, or speak. TB has long been considered an occupational hazard in the health care setting. However, it is inhalation exposure to aerosolized *M. tuberculosis* and not some other factor unique to the health care setting that places workers at risk of infection. Thus, any work setting where employees can reasonably be anticipated to encounter individuals with infectious TB also contains the occupational hazard of TB infection.

On December 21, 1992, the Labor Coalition to Fight TB in the Workplace (the Coalition) requested the Agency to issue nationwide enforcement guidelines to protect workers against exposure to TB in health care, criminal justice, and other high risk settings and to issue a Joint Advisory Notice on TB in conjunction with the Centers for Disease Control and Prevention (CDC) (Ex. 2). This petition was signed by the presidents of the Service Employees International Union (SEIU), the American Federation of State, County, and Municipal Employees (AFSCME), and the American Federation of Teachers (AFT), and was endorsed by 9 other unions. The petition included a list of provisions that the petitioners felt should be included in the guidelines, ranging from a written control plan and medical surveillance to anti-discrimination language and medical removal protection.

Eight months later, on August 25, 1993, the Coalition petitioned OSHA to initiate rulemaking for a permanent standard issued under § 655(b) of the Act to protect workers from occupational transmission of TB (Ex. 1). Citing the recent resurgence of TB and the emergence and increasing rate of new cases of multidrug-resistant TB (MDR–TB), the petitioners stressed the need for a substance-specific standard to address the hazards associated with occupational exposures to TB. The petitioners contended that the non-mandatory CDC TB Guidelines do not provide adequate protection because they are not fully or rigorously implemented in most workplaces. They also stated that in every outbreak of TB investigated by CDC, noncompliance with the Guidelines was evident.

In addition to a permanent standard, the petitioners also requested that OSHA immediately issue the nationwide enforcement guidelines that the Coalition had previously requested, and that OSHA promulgate an Emergency Temporary Standard (ETS) as an interim measure. The Coalition requested that the standard be applicable to all work settings where employees can reasonably anticipate contact with infectious TB. The petition included a discussion on occupational risk that included both the traditional high-risk occupations and other occupations such as sheet metal workers, postal workers, airline employees, teachers, and office workers.

Like the request for nationwide enforcement guidelines, the petition contained provisions that the petitioners requested be included in the standard. Examples include a facility hazard assessment and written exposure control plan, engineering and work practice controls, respiratory protection, medical surveillance (e.g., tuberculin skin testing) and counseling, post-exposure management, outbreak management, training, and recordkeeping.

On October 8, 1993, OSHA issued nationwide enforcement procedures for occupational exposure to TB. The compliance document contained the enforcement procedures that the Agency could and would use in certain work settings for protecting workers with occupational exposure to TB. In the compliance procedures, the Agency noted that although OSHA has no standard designed specifically to reduce occupational exposure to TB, the Agency has existing standards that apply to this hazard. For example, 29 CFR 1910.134 requires employers to provide respiratory protection equipment and 29 CFR 1910.145(f) requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1), the General Duty Clause of the Act, requires that each employer:

> * * * furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

On January 26, 1994, in response to their August 25 petition, Secretary of Labor Robert B. Reich informed the petitioners that OSHA was initiating rulemaking on a permanent standard to be issued under Section 6(b)(5) of the Act for occupational exposure to TB (Ex. 1B). At the same time, the petitioner's request for an ETS was denied. The Agency had determined that the available data did not meet the criteria for an ETS as set forth in Section 6(c) of the Act. However, OSHA committed to enforcing existing regulations and Section 5(a)(1) of the Act in certain work settings while preparing this standard.

On October 28, 1994 the CDC issued revised guidelines for preventing the transmission of tuberculosis in health care facilities (Ex. 4B). In addition, in June of 1995, the National Institute for Occupational Safety and Health (NIOSH) published revised certification procedures for non-powered air purifying particulate respirators (Ex. 7–261). As a result of changes in these two documents, OSHA issued revised enforcement policies and procedures relative to TB in February of 1996 (Ex. 7–260).

In October and November of 1995, OSHA held a series of meetings with stakeholder groups representing labor unions, professional organizations, trade associations, state and federal government, representatives of employers, as well as frontline workers from the various sectors anticipated to be covered by the proposed standard. During these meetings, participants provided input relative to the concepts and approaches OSHA was considering for the proposed tuberculosis standard.

In September of 1996, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Small Business Advocacy Review Panel was convened to consider the impact of OSHA's draft proposed tuberculosis standard on affected small entities. The panel, comprised of members from the Office of Advocacy of the Small Business Administration (SBA), the Office of Management and Budget (OMB), and OSHA, prepared a report based on the Panel's findings and recommendations with regard to comments on the standard received from small business employers. This report was submitted to the Assistant Secretary for OSHA for its consideration during the development of the standard (Ex. 12). OSHA's proposed standard reflects input generated during both the stakeholder meetings and the SBREFA review process.

Comparison of OSHA's Proposed Standard and CDC's Revised Guidelines

In preparing its proposed standard for TB, OSHA has relied heavily on the expertise of CDC. The Agency has consulted with CDC and has incorporated the basic elements of CDC's revised guidelines for preventing the transmission of *M. tuberculosis* in health care facilities in this proposed standard. Both CDC and OSHA rely on minimizing exposures and consequent transmission by identifying suspected infectious TB individuals and isolating them. The OSHA proposed standard includes the following CDC components: written exposure control plans, procedures for early identification of individuals with suspected or confirmed infectious TB, procedures for initiating isolation of individuals with suspected or confirmed infectious TB or for referring those individuals to facilities with appropriate isolation capabilities, procedures for investigating employee skin test conversions, and education and training for employees. In addition, OSHA has incorporated CDC recommendations for engineering control measures such as the use of negative pressure for AFB isolation rooms or areas, daily monitoring of negative pressure while AFB isolation rooms are in use for TB, HEPA filtration of recirculated air from AFB isolation rooms, and periodic maintenance and monitoring of engineering controls. With regard to respiratory protection, OSHA has adopted CDC's standard performance criteria for the selection of respiratory protection devices appropriate for use against *M. tuberculosis.* And finally, where appropriate, OSHA has attempted to assure that where certain practices are required by OSHA's proposed standard, e.g., tuberculin skin testing and medical management and follow-up of employees who acquire TB infections or active disease, these practices are conducted according to the current recommendations of the CDC. Therefore, OSHA's proposed standard for occupational exposure to TB closely follows CDC's recommended elements for a TB infection control program.

However, there are some minor differences between OSHA's proposed standard and CDC's guidelines that go

beyond the obvious enforcement distinction between a guideline and a standard. These differences are found primarily in the areas of risk assessment, medical surveillance and respiratory protection. Even so, OSHA believes that despite these differences the vast majority of the provisions included in this proposed standard closely track the recommendations of the CDC. The following discussion identifies where these differences occur and describes the extent of these differences and the degree to which they impact on employers' responsibilities under the proposed standard.

Risk Assessment

As a part of its guidelines, CDC recommends that a risk assessment be conducted in all facilities to assess the risk of transmission of *M. tuberculosis* in each facility. This risk assessment is to be conducted using information such as the profile of TB in the community, the number of suspected and confirmed cases of TB among patients and health care workers, results of health care worker tuberculin skin testing (i.e., conversion rates), and observation of TB infection control practices. Using the results of this risk assessment, appropriate infection control interventions can then be selected based on the actual risk in the facility. CDC includes a protocol for conducting this risk assessment in which there are 5 categories of risk: ''minimal'', ''very-low'', ''low'', ''intermediate'', and ''high''. Each category from ''minimal'' to ''high'' has an increasing number of infection control interventions that are recommended for each particular level of risk.

OSHA, however, has chosen a simpler approach and is not requiring employers to conduct such a risk assessment. Consistent with other standards, OSHA has determined that employees in the work settings and employees providing services set forth in the scope section are at risk of occupational exposure to TB. Their employers are required to conduct an exposure assessment to determine which employees have occupational exposure, i.e., reasonably anticipated contact with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis.* The standard then specifies the provisions applicable for the employees whom the employer has identified as having occupational exposure. In addition, consistent with its approach in other standards, OSHA does not require that individual risk assessments be conducted by each work setting covered under the standard, as they may be too difficult and burdensome for employers to prepare. Also, many work settings will have too few occupationally exposed employees to do an accurate risk assessment. Finally, conducting the risk assessments in order to determine applicable duties may require a level of expertise some facilities lack, making enforcement burdensome for the Agency.

OSHA realizes, however, that in many work settings, very few individuals with suspected or confirmed infectious TB may be seen and that in many of those work settings, individuals with suspected or confirmed infectious TB will be transferred to other facilities that are better equipped to provide services and care using appropriate TB isolation precautions. Because there is likely to be less risk of transmission of *M. tuberculosis* in those situations, OSHA believes that it is possible to make the standard less burdensome for the employers with these types of work settings while still maintaining worker protection.

For example, an employer who can demonstrate that his or her facility or work setting: (1) Does not admit or provide medical services to individuals stwith suspected or confirmed infectious TB, (2) has not had any individuals with confirmed infectious TB within the work setting within the last 12 months, and (3) is located in a county that, in the past 2 years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year, does not have to comply with all provisions of the standard. Such employers would only be responsible for compliance with certain provisions, e.g., a written exposure control plan, a baseline skin test and medical history, medical management and follow-up after exposure incidents, medical removal protection where necessary, employee training, and recordkeeping. These provisions are very similar to the recommendations of the CDC for facilities classified as having ''minimal risk,'' i.e., no TB in the community or in the facility. The only major difference is that CDC does not recommend baseline skin testing. However, CDC does state that baseline skin testing would be advisable so that if an unexpected exposure does occur, conversion could be distinguished from positive skin test results caused by previous exposures.

Medical Surveillance

In the area of medical surveillance, the main differences between OSHA and CDC are related to tuberculin skin testing. OSHA requires baseline skin testing for all employees whom the employer identifies as having occupational exposure. CDC recommends baseline skin testing for all employees with potential exposure except those who work in facilities that fall into CDC's ''minimal risk'' category. However, CDC notes that even for employees in ''minimal risk'' facilities, it may be advisable to perform baseline skin testing so that if unexpected exposures do occur, conversions can be distinguished from positive skin test results caused by previous exposures. Thus, there is little difference between OSHA requirements and CDC recommendations with regard to baseline skin testing.

Relative to periodic skin testing, OSHA requires periodic re-testing for all employees identified as having occupational exposure who have negative skin tests except for the employees of those employers who have no TB in the community and who have not encountered any individuals with confirmed infectious TB in their work settings within the past year. CDC recommends re-testing for employees in the ''low'', ''intermediate'', and ''high'' risk categories. According to the CDC guidelines, periodic re-testing is not necessary for employees in the ''minimal'' risk category or the ''very-low'' risk categories. CDC's periodic skin test recommendations for the ''minimal'' risk category are similar to OSHA's limited program for employers who do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have not encountered any confirmed infectious TB in their work setting, and are located in a county that, in the past 2 years, has reported 0 cases of confirmed infectious TB in one year and fewer than 6 cases in the other year. OSHA is different from the CDC in that employees in a ''very-low risk category'' are required to be periodically retested. However, CDC notes that even in the ''very-low'' risk category, employees who are involved in the initial assessment of individuals in emergency departments and admitting areas may have potential exposure and thus may need periodic re-testing.

Another difference between CDC and OSHA is the frequency of the re-testing. This is primarily due to the fact that OSHA's required frequencies are based on the type of work that employees do that result in exposures whereas CDC's recommendations are based more on evidence of conversions. For example, OSHA requires re-testing every six months for all employees who (1) enter AFB isolation rooms or areas, (2) perform high-hazard procedures, (3)

transport individuals with suspected or confirmed infectious TB in an enclosed vehicle, or (4) work in intake areas where early identification procedures are performed (e.g., emergency departments, admitting areas) in facilities where 6 or more individuals with confirmed infectious TB have been encountered in the past 12 months. For all other employees with occupational exposure, re-testing is required every 12 months. In comparison, CDC recommends re-testing every year for employees in ''low'' risk categories, every 6–12 months for employees in ''intermediate'' risk categories, and every 3 months for employees in ''high'' risk categories. Under CDC recommendations, employees in ''low'' risk categories who enter AFB isolation rooms or areas or employees who transport individuals with suspected or confirmed infectious TB in an enclosed vehicle would be re-tested every 12 months. However, under OSHA requirements, those same employees would be required to be re-tested every six months. Thus, OSHA is more protective than CDC in this case.

OSHA also would require that employees who perform high-hazard procedures or who work in intake areas where early identification procedures are performed in facilities that encounter 6 or more individuals with confirmed infectious TB be re-tested every six months. Under CDC's Guidelines employees in areas in which cough-inducing procedures are performed on individuals who may have active TB are recommended to follow an intermediate risk protocol. Similarly, CDC recommends that an intermediate risk protocol be followed in areas where more than six individuals who may have active TB receive initial assessment and diagnostic evaluation (e.g., ambulatory care, emergency departments, admitting areas). CDC recommends re-testing every 6–12 months for employees in intermediate risk categories. OSHA would require re-testing every 6 months for the two situations above, which is very similar to CDC's recommendation of re-testing every 6–12 months.

CDC is more protective in its recommendations for employees in the ''high'' risk category. These employees are recommended to be re-tested every 3 months. OSHA does not have a requirement for re-testing employees every 3 months. However, after an exposure incident, OSHA requires that a skin test be administered as soon as feasible and again 3 months after the exposure incident, if the first skin test is negative. Since it is possible that an exposure incident(s) could be the type of event that would cause an employee(s) to be included in the ''high'' risk category as defined by CDC, OSHA requirements, to some extent, track the CDC recommendations for a higher frequency of periodic skin testing.

With regard to two-step testing, both OSHA and CDC require or recommend two-step testing at the time baseline skin testing is administered. Also, both OSHA and CDC add that two-step testing is not necessary if the employee has had a documented negative skin test within the last 12 months. CDC is different from OSHA in that its Guidelines imply that two-step testing can be discontinued if there is evidence of a low frequency of boosting in the facility. OSHA's proposed standard does not allow such an exemption, i.e., for each employee who must have a baseline skin test at the time of the initial medical examination, the skin test must include a two-step test unless the employee has a documented negative test within the last 12 months, regardless of the frequency of boosting in the facility. The value of two-step skin testing is that it enables one to distinguish true conversions from boosted reactions. OSHA believes that this is important to know for each employee because if the employee is incorrectly identified as having converted, he or she may needlessly be subjected to preventive therapy that may have toxic side effects of its own. Since it is important to know the true skin test status for each employee, OSHA has preliminarily concluded that it is inappropriate to allow the overall frequency of boosting among employees in a facility to dictate whether any one employee receives two-step testing at the time of his or her baseline testing.

Respiratory Protection

OSHA requirements and CDC recommendations for respiratory protection are very similar. A respirator is a personal protective equipment device worn over the nose and mouth of the employee that filters certain airborne contaminants from the inhaled air. OSHA has adopted CDC's performance criteria for respirators appropriate for use for TB. Also, both OSHA and CDC have similar requirements or recommendations that respirators be worn when entering an isolation room, when performing cough-inducing procedures or aerosol-generating procedures on an individual with suspected or confirmed infectious TB, when repairing or maintaining air systems that may contain aerosolized *M. tuberculosis*, when transporting an individual with suspected or confirmed infectious TB in an enclosed vehicle and when working in a residence where an individual with suspected or confirmed infectious TB is known to be present. However, OSHA also requires that respirators be worn when employees are transporting individuals with suspected or confirmed infectious TB within the facility if those individuals are not masked (e.g., a surgical mask or a valveless respirator). CDC does not have a similar recommendation for respiratory protection while transporting individuals within the facility, but CDC does recommend, and assumes to some extent, that individuals with suspected or confirmed infectious TB are masked whenever they are outside an isolation room. In addition, OSHA requires that respirators be worn when employees work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined. For example, this provision would cover employees such as those who work in admitting areas and must attend to unmasked individuals with suspected or confirmed infectious TB while those individuals are awaiting transfer. These types of employees are likely to be found in facilities that would meet CDC's definition of ''minimal'' risk. CDC states that respiratory protection is not necessary for employees in the ''minimal'' risk category. However, again, CDC recommends that if an individual with suspected or confirmed infectious TB is identified in a ''minimal'' risk facility, the individual should be masked while he or she is awaiting transfer to another facility, thus obviating the need for respiratory protection. OSHA, on the other hand, cannot require employers to mask clients or patients in a facility, and the Agency must therefore include provisions for respirator use to protect potentially exposed employees. However, consistent with CDC, OSHA proposes not to require respirators where the employer elects, as a part of his or her own administrative policies, to mask individuals with suspected or confirmed infectious TB. Thus, when individuals with suspected or confirmed infectious TB are masked while they are awaiting transfer to another facility or while they are being transported within the facility, employees would not be required by the standard to wear a respirator.

In some instances, the CDC may be more protective than OSHA with regard to respiratory protection. The CDC states that the facility's risk assessment may identify selected settings where the

estimated risk of transmission of *M. tuberculosis* may be such that a level of respiratory protection exceeding the standard performance criteria is appropriate (e.g., more protective negative pressure respirators, powered air purifying respirators). The examples given of such selected settings are a bronchoscopy performed on an individual suspected of having TB and an autopsy performed on a deceased person suspected of having had active TB at the time of death. OSHA does not have a similar requirement for more protective respiratory protection. Respirators meeting the minimal performance criteria laid out by the standard would be required by OSHA for employees performing all high-hazard procedures, including bronchoscopies and aerosol-generating autopsy procedures.

IV. Health Effects

Introduction

For centuries Tuberculosis (TB) has been responsible for the death of millions of people throughout the world. It was not until 1882, however, that Robert Koch identified a species of bacteria, *Mycobacterium tuberculosis (M. tuberculosis),* as the cause of TB.

TB is a communicable disease that usually affects the lungs. The airborne route is the predominant mode of transmission, a situation created when individuals with infectious TB discharge the bacilli from the lungs when coughing, sneezing, speaking or singing. Some individuals who breathe contaminated air become infected with TB. Most often, the immune system responds to fight the infection. Within a few weeks, the infected lesions become inactive and there is no residual change except for possible lymph node calcifications. These individuals will have a positive skin test result. They will harbor the infection for life. At some time in the future, the infection can progress and can become an active disease, with pulmonary infiltration, cavitation, and fibrosis, possibly causing permanent lung damage and even death. With some exceptions, however, TB is treatable with antimicrobial drugs. If the active TB is treated early, there will be minimal residual lung damage. For this reason, individuals who have a TB exposure incident and develop a TB infection are treated to prevent progression to active TB disease.

With the introduction of antimicrobial drug treatment in the 1940s and the creation of programs in the United States such as the U.S. Public Health Service's Tuberculosis Program, there began a decline in the incidence of active TB cases in the U.S. From 1953, when active cases began to be reported in the U.S., until 1984, the number of annual reported cases declined 74%, from 84,304 (53 per 100,000) to 22,255 (9.4 per 100,000) (Ex. 7–50). However, this steady decline in TB cases did not continue. Instead, from 1985 through 1992, the number of reported TB cases increased 20.1% from 22,201 to 26,673 (10.5 cases per 100,000) (Ex. 6–13).

This resurgence in TB brought to attention a number of problems in the existing TB control programs. The direction of resources to areas with the highest increase in active cases has caused this increase to decline. The number of cases reported for 1995 indicates that the rate of active TB has returned to its 1985 levels. In 1995, a total of 22,813 cases of TB (8.7 per 100,000) was reported to CDC (Ex. 6–34). While this represents a decline in active TB, the 1995 rate is still two and one half times greater than the target case rate of 3.5 per 100,000 for the year 2000 and approximately 87 times the goal of less than one case per million population by the year 2010 proposed by the Advisory Committee on the Elimination of Tuberculosis (Ex. 6–19).

TB continues to be a national problem. Each year, cases of active disease are reported in every state in the Nation and in a substantial majority of counties nationwide. CDC estimated in 1990 that approximately 10 million people were infected with the tuberculosis bacterium and that approximately 90% of the new cases of active disease that arise in the United States come from this already infected group (Ex. 7–52). Given the recent resurgence of TB, it is likely that a new population of individuals has been infected as well. Of great concern are strains of *M. tuberculosis* that have emerged that are resistant to several of the first-line anti-TB drugs normally used to treat TB infection and disease (e.g., isoniazid and rifampin). This drug-resistant form of the disease, referred to as multidrug-resistant TB or MDR–TB, is more often a fatal form of TB due to the difficulty in finding antimicrobial drugs to stop the bacteria's growth and progressive tissue destruction. In addition, individuals with MDR–TB often remain infectious for longer periods of time due to delays in diagnosing resistance patterns and initiating appropriate treatment. This, in turn, increases the risk that infectious individuals will transmit the organism to other persons coming in contact with them.

Most of the decreases in reported cases of TB since 1992 have occurred in areas such as New York City, where resources have been invested to improve or initiate TB control provisions, such as those outlined in OSHA's proposed standard. However, the 1995 statistics show that over the course of four years there is substantial variability in the increases and decreases of cases reported by each state for any given year (Ex. 6–34). In 1995, 15 states reported an increase in the number of TB cases compared with 1994. In addition, a recent study has shown that MDR–TB has spread to patients in Florida and Nevada, and to health care workers in Atlanta, Georgia and Miami, Florida. Moreover, one individual with MDR–TB infected or caused disease in at least 12 people in a nursing home in Denver, Colorado (Ex. 7–259). This study shows very clearly the ability of TB to be spread to different areas of the country. This is to be expected given the mobile nature of today's society and the frequency with which people travel. Immigration also contributes to the incidence of the disease. For example, while the number of active TB cases has decreased among U.S. born persons, the number of foreign born persons reported with TB has increased 63% since 1986, with a 5.4% increase in 1995 (i.e., from 7,627 cases in 1994 to 8,042 cases in 1995). Thirty to fifty percent of these cases were diagnosed 1 to 5 years after the individual enters the U.S. (Ex. 6–34). Thus, tuberculosis continues to be a public health problem throughout the United States.

The following discussion will briefly describe the basic concepts and terminology associated with TB as well as common factors that facilitate its transmission from one individual to another. This discussion will also include a review of studies relating to the occupational transmission of TB.

Background

TB is a contagious disease caused by the bacterium *M. tuberculosis.* Infection is generally acquired by the inhalation of airborne particles carrying the bacterium. These airborne particles, called droplet nuclei, can be generated when persons with pulmonary or laryngeal tuberculosis in the infectious state of the disease cough, sneeze, speak or sing.

In some individuals exposed to droplet nuclei, tuberculosis bacilli enter the lung and establish an infection (Ex. 7–52). Once in the alveoli, the tuberculosis bacilli are taken up by alveolar macrophages and spread throughout the body by the lymphatic system, until the immune response limits further growth (usually a period of two to ten weeks). In most cases the tuberculosis bacilli are contained by the

immune response. Macrophage cells engulf the bacteria, which limits the spread of the bacilli. Initial lesions from infection heal; however, small calcifications called tubercles are formed and may remain a potential site of later reactivation.

Individuals in this state are infected with TB. They will show a positive skin test and they are at risk of developing active TB, a risk they carry throughout their lifetime. In many cases, as described below, preventive therapy is initiated with anti-TB drugs to prevent the progression to active TB disease. These drugs are toxic and may cause adverse effects such as hepatitis. Severe preventive therapy-associated hepatitis cases have necessitated liver transplants and in some cases have resulted in death (Ex. 6–10).

When the bacilli are not contained by the immune system, they continue to grow and invade the tissue, leading to the progressive destruction of the organ involved, which in most cases is the lung, i.e., pulmonary tuberculosis. The inflammatory response caused by the disease produces weakness, fever, chest pain, cough, and, when blood vessels are eroded, bloody sputum. Also, many individuals have drenching night sweats over the upper half of the body several times a week (Ex. 5–80). The extent of disease varies from minimal symptoms of disease to massive involvement with extensive cavitation and debilitating constitutional and respiratory symptoms. Since tuberculosis bacilli are spread throughout the body after the initial infection, other organs may also be infected and disease may occur at sites outside the lung, i.e., extrapulmonary tuberculosis.

There are two general stages of TB, tuberculosis infection and active tuberculosis disease. Individuals with tuberculosis infection and no active disease are not infectious. These tuberculosis infections are asymptomatic or subclinical and are only detected by a positive response to a tuberculin skin test. However, there are some individuals whose immune system is impaired and cannot mount a sufficient response to skin test antigens, i.e., they are anergic. Such individuals may be infected, although they do not show a positive response to the skin test. Individuals with tuberculosis infection and no disease would have negative bacteriologic studies and no clinical or radiographic evidence of tuberculosis disease. However, these individuals are infected for life and are at risk of developing active TB in the future.

Anti-tuberculosis drugs may be used for individuals with TB infection but who do not have active disease. In these cases, the antimicrobials are used as preventive therapy to prevent the onset of active disease. Because of the toxicity associated with the antimicrobials, preventive therapy may not be appropriate for all infected individuals. Various factors are considered to determine whether an infected individual is an appropriate candidate for preventive therapy (e.g., age, immune status, how recently the infection occurred, and other high-risk factors associated with TB) (Ex. 7–52, pg. 17). Isoniazid is currently the only drug that has been well tested in humans for its efficacy as preventive therapy (Ex. 7–50, pg. 61). However, serious side effects may result from isoniazid. A study in New York for the years 1991 to 1993 examined cases of hepatitis induced by isoniazid preventive therapy. In this study, 10 patients undergoing preventive therapy for TB were identified at a transplant center. Eight of these patients had developed hepatitis from isoniazid. Five received a liver transplant; the other three died while awaiting a liver donor. In addition, one of the transplant patients died after transplantation. Thus, preventive therapy may carry considerable risks for infected individuals.

In those cases where isoniazid cannot be tolerated by the patient or where it is suspected that infection resulted from exposure to isoniazid-resistant strains of *M. tuberculosis*, rifampin may be recommended for preventive therapy. Considerations for such alternative drug therapies are made on a case-by-case basis by the health care provider based on the medical and case history of the infected patient. Rifampin has adverse side effects as well. However, preventive therapy using rifampin has not been followed as well as that involving isoniazid and therefore, its side effects are less well characterized.

Individuals with active TB have clinical and/or radiographic evidence of disease. The initial laboratory method for diagnosing TB is the Acid Fast Bacilli (AFB) smear. This is a quick and easy technique in which body fluids, typically sputum samples, from individuals with suspected TB are examined for mycobacteria. However, this type of test only permits a presumptive diagnosis of TB since the test cannot distinguish between tuberculosis mycobacteria and other non-tuberculosis mycobacteria. Chest X-rays may also be used to diagnose active TB; however, some individuals with TB may have X-ray findings that are atypical of those usually associated with TB (e.g., HIV infected individuals). The diagnosis of clinically active TB is most definitively established by the isolation of *M. tuberculosis* in culture. However, it may take three to six weeks or longer from obtaining a culture to getting a result.

Individuals with active TB disease may be infectious, especially if they are untreated or inadequately treated and if the disease is in the lungs. The clinical symptoms of pulmonary TB include loss of appetite, weight loss, fatigue, fever, night sweats, malaise, cough with productive sputum and/or blood, and chest pain. The extent of the disease varies from very minimal symptoms to extensive debilitating constitutional and respiratory symptoms. If untreated, the pulmonary TB follows a chronic and progressive course in which the tissue is progressively destroyed. It has been estimated that approximately 40 to 60% of untreated cases result in death (Exs. 5–80, 7–50, and 7–66). However, even among cured cases of TB, long-term damage can result, including impaired breathing due to lung damage (Ex. 7–50, pg. 31).

Approximately 90% of immunocompetent adults who are infected do not develop active TB disease. However, for 10% of infected immunocompetent adults, either directly after infection or after a latency period of months, years or even decades, the initial infection progresses to clinical illness, that is, active TB (Ex. 4B). The risk of developing active TB is increased for individuals whose immune system is impaired (i.e., immunocompromised). Such individuals include persons undergoing treatment with corticosteroid or immunosuppressive drugs (e.g., persons with organ transplants or persons undergoing chemotherapy for cancer), persons suffering from malnutrition or chronic conditions such as asthma and emphysema, and persons infected with the human immunodeficiency virus (HIV).

The main first-line drugs currently used to treat active TB are isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin. Combinations of these antimicrobials are used to attack the tuberculosis bacilli in the body. Recommended treatment regimens include two or more drugs to which the bacilli are susceptible, because the use of a single drug can lead to the development of bacilli resistant to that drug (Ex. 5–85). Treatment with these first-line drugs involves a two-phase process: an initial bactericidal phase for the quick elimination of the bulk of bacilli from most body sites and a longer-term sterilizing phase for eliminating the remaining bacilli.

Different regimes of drug treatment (i.e., the types of drugs and frequency of administration) are recommended depending on the medical history of the patient involved and the results of drug susceptibility testing. The U.S. Public Health Service has recommended options for the initial therapy and dosage schedules for the treatment of drug-susceptible TB (Ex. 4B). While these antimicrobials are effective in the treatment of active TB, some of these drugs also have toxic potential. Adverse side effects of these drugs include hepatitis, peripheral neuropathy, optic neuritis, ototoxicity and renal toxicity (Ex. 7–93). Thus, patients undergoing TB therapy must also be monitored for drug toxicity that may occur from anti-tuberculosis drugs.

Individuals with active disease who are infectious may need to be hospitalized in order to provide isolation so that they will not infect other individuals. After the initiation of treatment for active TB, improvement of the disease can be measured through clinical observations such as loss of fever, reduction in coughing, increased appetite and weight gain. A reduction in the number of bacilli in sputum smears also indicates improvement. Three consecutive negative sputum smears generally indicate that the individual is no longer infectious. However, decisions about infectiousness are usually determined on a case-by-case basis after taking a number of factors into consideration, such as the presence of cough, the positivity of sputum smears, and the status or response to chemotherapy. Although no longer infectious to other individuals, the individual undergoing treatment still has tuberculosis disease and must continue treatment. Discontinuing or erratically adhering to the treatment regime can allow some of the bacilli to survive such that the individual will be at risk of becoming ill and infectious again (Ex. 7–52, p. 25).

Not all strains of the tuberculosis bacilli are susceptible to all of the antimicrobials used to treat TB. In some instances, drug-resistant forms of *M. tuberculosis* may emerge. Drug resistance may emerge by 1 of 3 mechanisms (Exs. 5–85; 7–50, pp. 44–47). Drug-resistant TB may occur naturally from random mutation processes, i.e., primary resistance. In addition, drug-resistant TB may result due to inadequate or erratic treatment, i.e., acquired resistance. In these cases, erratic or inadequate treatment allows the tuberculosis bacilli to become resistant to one or several of the drugs being used. Finally, drug-resistant TB may result due to the active transmission of drug-resistant TB from an individual already infected with drug-resistant strains of the tuberculosis bacteria, i.e., transmitted resistance. In recent years, drug-resistant forms of TB have emerged that are resistant to two or more of the first-line drugs used to treat TB, such as isoniazid and rifampin, two of the most effective anti-TB drugs. These drug-resistant forms of the disease are referred to as multidrug-resistant TB or MDR–TB. MDR–TB represents a significant form of drug-resistant TB from a public health standpoint, since its resistance to the first-line drugs used for therapy complicates finding adequate therapy regimens that will control the bacilli's growth.

Treatment of drug-resistant TB is determined on a case-by-case basis, using information from the patient's medical history and drug susceptibility testing. The recommended course of treatment will vary depending on the drugs to which the bacilli are susceptible. Compared to conventional TB drug therapy, MDR–TB, in general, requires more complex interventions, longer hospitalization and more extensive laboratory monitoring. The risk of death from such infections is markedly increased. For example, from January 1990 through September 1992, the CDC investigated eight outbreaks of MDR–TB. In these outbreaks, 253 patients were infected, of whom approximately 75% died (Ex. 3–38–A). Many of these were immunocompromised due to infection with HIV. The interval from the time of TB diagnosis to the time of death ranged from 4 to 16 weeks, with a median time of 8 weeks.

Factors Affecting Transmission

A number of factors can influence the likelihood of acquiring a tuberculosis infection: (1) The probability of coming into contact with an individual with infectious TB, (2) the closeness of the contact, (3) the duration of the contact, (4) the number of tuberculosis bacilli in the air, and (5) the susceptibility of the uninfected individual. Several environmental conditions can influence the likelihood of infection. For example, the volume of shared air space, the amount of ventilation, the presence or absence of sunlight, the humidity and the crowded nature of the living quarters. These types of factors will affect the probability of acquiring a tuberculosis infection after being exposed to an individual with infectious TB. MDR–TB is not more contagious than drug-susceptible forms of the disease. However, due to time delays in diagnosing resistance patterns and initiating adequate treatment, individuals with active MDR–TB may remain infectious for longer periods of time. Consequently, the likelihood that they will infect other noninfected individuals is increased.

Once infection occurs, other factors may influence the probability of progressing to the active form of disease. As previously discussed, 10% of immunocompetent adults infected with TB develop active TB. Three to five percent of untreated immunocompetent adults develop active TB within the first year after infection (Ex. 7–50, pg. 30; 7–52). Thus, recently infected individuals have the highest risk of developing active TB. This risk is increased for individuals whose immune system is impaired (e.g., persons being treated with immunosuppressive or glucocorticoid drugs, persons with chronic conditions such as asthma or emphysema or persons infected with the HIV). The probability of developing active disease can also be influenced by other conditions that may alter immune function such as overall decreased general health status, malnutrition, and increasing age.

The resurgence of TB in the United States from 1985 to 1992 has been attributed to a number of interacting factors: (1) The inadequate control of disease in high prevalence areas; (2) the increase in poverty, substance abuse, poor health status and crowded substandard living conditions; and (3) the growing number of inmates, residents of homeless shelters, elderly persons in long-term care facilities, persons with HIV infection and immigrants from countries with a high prevalence of TB infection (Ex. 7–50). This increase has begun to decline, with the 1995 case levels approaching the 1985 levels. However, a main reason for this decrease is the implementation of TB control measures, like those proposed in this standard, in selected areas of the country such as New York City. OSHA believes that implementation of such measures is necessary to prevent a resurgent peak such as that observed from 1985 to 1992 and to realize the goal set out by the National Advisory Committee for the Elimination of Tuberculosis. The following discussion describes some of the health effects data related to occupational exposure to TB and illustrates how the presence of TB control measures influences TB infection and disease.

Occupational Exposure

Exposure to TB in the health care setting has long been considered an occupational hazard. With the steady

decline in reported TB cases from 1953 to 1985, some of the concern for occupational exposure and transmission also declined. However, from 1985 to 1992 the number of reported cases of TB increased. In addition, in recent years, several outbreaks of TB among both patients and staff in hospital settings have been reported to the CDC. These outbreaks have been attributed to several factors: (1) Delayed recognition of active TB cases, (2) delayed drug susceptibility testing, (3) inadequate isolation of individuals with active TB (e.g., lack of negative pressure ventilation in isolation rooms, recirculation of unfiltered air, and allowing infectious patients to freely move in and out of isolation rooms), and (4) performance of high-risk procedures on infectious individuals under uncontrolled conditions (Ex. 7–50). In addition to hospitals, outbreaks of TB have also been reported among the patients, clients, residents and staff of correctional facilities, drug treatment centers, homeless shelters and long-term health care facilities for the elderly. The factors contributing to the outbreaks in these other occupational settings are very similar to those factors contributing to the outbreaks in hospital settings (i.e., delayed recognition of TB cases and poor/inadequate ventilation for isolation areas).

The following is a discussion of some of the studies that have examined occupational transmission of TB. A large proportion of the available information comes from exposures occurring in hospitals, in part because this occupational setting has been recognized for many years as an area of concern with regards to the transmission of TB. However, in more recent years this concern has spread to other occupational settings which share factors identified in the hospital setting as contributing to the transmission of disease. The following sections will include a discussion of some of the historical data from the hospital setting, as well as the more recent data that have been developed in hospitals and other occupational settings where the transmission of TB has occurred as a result of the recent resurgences in the number of active TB cases.

Hospitals—Prior to 1985

Even prior to the recent resurgence of TB in the general population, studies have shown an increased risk of transmission of TB to health care workers exposed to individuals with infectious TB. These studies clearly demonstrate that in the absence of appropriate TB control measures (e.g., lack of early identification procedures, lack of appropriate engineering controls), employees exposed to individuals with infectious TB have become infected and in some cases have developed active disease.

In 1979, Barrett-Connor (Ex. 5–11) examined the incidence of TB among currently practicing physicians who graduated from California medical schools from approximately 1950 to 1979. Through mailed questionnaires, physicians were asked to provide information that included their year of graduation from medical school, BCG vaccination history, history of active TB, results of their tuberculin skin testing, and the number of patients they were exposed to with active TB within the past year. They were also asked to classify themselves as tuberculin positive or negative and to indicate the year of the last negative and first positive tuberculin test.

Of the 6425 questionnaires mailed out, 4140 responses were received from currently practicing physicians. Twelve percent of the physicians had received the BCG vaccine. Sixty-one percent of the unimmunized physicians, who also had no history of active tuberculosis, considered themselves to be tuberculin negative. A total of 1542 (42%) reported themselves as having a positive response to the tuberculin skin test, with approximately 44 percent of those tuberculosis infections occurring before entering medical school. Of those infections occurring before entering medical school, approximately eight percent were reported as having been a result of contact following work experience in the hospital prior to entering medical school. For those physicians infected either during or after medical school, the sources of infection were reported as occurring as a result of a known patient contact (45.1%), an unknown contact (41.5%) and a non-patient contact (13.4%). In some cases, the nonpatient contact was reported as another physician or another hospital employee. Approximately one in ten of the physicians infected after entry into medical school developed active TB disease.

The authors also examined the incidence of infection, measured as the conversion rates in those remaining negative at the end of different time intervals (e.g., the last three years of medical school and five to 10 years after graduation). This examination indicated that from 1950 to 1975, there was a 78% decrease in tuberculin conversion rates despite the expanding pool of susceptible medical students (i.e., an increasing number of medical students who were tuberculin negative). Yet despite this overall decrease in infection rates over a 25 year period, tuberculin conversion rates among recent graduates exceeded 1% per year and age-specific infection rates among all the physicians studied were more than twice that of the U.S. population at comparable ages. The authors did not obtain information from the physicians on what type of infection control measures were being used in the facilities where they acquired their infections.

A similar analysis by Geisleler et al. (Ex. 7–46) evaluated the occurrence of active tuberculosis among physicians graduating from the University of Illinois medical school between the years 1938 and 1981. This study, also conducted by questionnaire, reported that among 4575 physicians questioned, there were 66 cases of active TB, of which 23% occurred after 1970. Sixty-six percent of the cases occurred within 6 years of graduation. In addition, the authors reported that in most years the incidence of TB was greater among these physicians than the general population.

Weiss (Ex. 7–45) examined tuberculosis among student health nurses in a Philadelphia hospital. From 1935 to 1939, before the introduction of anti-TB drugs and the beginning of the general decline of TB in the United States, 100% conversion rates were observed among those students who were initially tuberculin negative. For example, of 643 students admitted, 43% were tuberculin negative. At the end of only 4 months, 48% were tuberculin positive. At the end of 1 year, 85.9% were tuberculin positive and by the end of the third year 100% were positive. Of those students who converted during their student nursing tenure, approximately 5 percent developed active TB disease.

A decline in the rate of infection was observed over the next 36 years among student nurses at this hospital. The rates of infection were followed for ten classes of student nurses from 1962 to 1971. The students had little contact with patients during their first year but spent 4 weeks of their second year of training on the tuberculosis wards. Among those students initially tuberculin negative, the average conversion rate was 4.2% over the nine year period, ranging from 0 to 10.2%. Of the students who converted, 0.6% developed active TB disease. The authors attributed the decreases in conversion rates to not only the general decrease in TB disease in the community, but also to the increased efficiency of surveillance of patients entering the hospital for the early identification of potential cases of TB and the increased efficiency of isolation

for TB patients. Despite the dramatic decreases in conversion rates among these student nurses, conversion rates were observed at levels as high as 10% for a given year, indicating that while the infection rates had decreased substantially since 1939, there still remained a significant amount of occupational transmission of TB in 1971. Moreover, this study shows that short term exposure, i.e., 4 weeks, is capable of infecting hospital employees.

Similar rates of conversion among hospital employees initially tuberculin negative were observed in a 1977 study by Ruben et al. (Ex. 7–43) which analyzed the results of a tuberculin skin testing program 31 months after its inception at a university hospital in Pittsburgh. Of 626 employees who were tested twice with the tuberculin skin test, 28 (4.5%) converted from negative to positive. The employees were classified as either having a ''presumed high degree of patient exposure'' or a ''presumed low degree of patient exposure''. Employees presumed to have high patient exposure included nurses, X-ray and isotope laboratory personnel and central escort workers. Employees presumed to have low exposure included secretaries, persons in housekeeping and dietary work, and business office, laundry and central supply personnel. The rates of conversion for employees with presumed high exposure (6%) and for employees with presumed low exposure (8%) were not significantly different. However, this study excluded physicians and medical and nursing students. These groups of employees would also presumably have had high exposure to patients since they are often the hospital staff most directly involved in administering patient care. Had these employees been included the number of conversions among employees with presumably high exposure may have been significantly increased.

The study was not designed to determine the source of exposure for any of the employees who converted. However, the authors suggested that the high level of conversions among those employees with presumed low exposure to patients may have resulted from exposures at home. A majority of this group was comprised of housekeeping staff who were of low socio-economic status. The authors also suggested that unrecognized cases of tuberculosis may be playing an important role in the occupational transmission of TB in the hospital.

Unrecognized cases of TB have been shown to play a significant role in the outbreak of TB in a general hospital. In 1972, Ehrenkranz and Kicklighter (Ex. 5–15) reported a case study in which 23 employees converted after exposure to a patient with an undetected case of tuberculosis bronchopneumonia. In this study, the source case was an individual who was admitted to the emergency room with pulmonary edema. Upper lobe changes of the lung were noted in the chest X-ray, and TB was mentioned as a possible cause. However, no sputum cytology was conducted. The patient spent 3 hours in the emergency room, 57 hours in a private room and another 67 hours in intensive care until his death. Treatment of the patient included intubation with an endotracheal tube and vigorous nasotracheal suctioning. It was only upon microscopic examination of tissue samples of the lung and lymph nodes after the autopsy of the patient that tuberculosis mycobacteria were detected.

Employees who worked in the emergency room, the intensive care unit and on the floor of the private room (NW 3) and who were also tuberculin negative before the admission of the patient, were retested to detect possible conversion. In addition, 21 initially tuberculin negative employees on an adjacent floor (NW 2) were also retested. Of the 121 employees tested, 24 were identified as having converted to positive status (21 working on NW 3, 2 working in the intensive care unit and 1 working on NW 2). No conversions were observed among those working in the emergency room.

The employees who were retested were classified as either having close contact (e.g., providing direct care), little contact (e.g., more distant contact), unknown contact (e.g., no record or recollection of contact) or indirect contact (e.g., in the same room a day or two after the patient's stay). Conversions occurred in 50% (13 of 26) of those employees with close contact, 18.5% (6 of 33) of those with little contact, 21.4% (3 of 14) of those with unknown contact and 3.7% (1 of 29) of those with indirect contact.

While the majority of conversions seems to have occurred in those employees on NW 3 who had close or little contact, there also were employees with more distant contact who were infected. An analysis of the ventilation of NW 3 indicated that the central air conditioning recycled 70% of the air with no high efficiency filter and no record of balancing the air conditioning system, thus allowing the air from the patients' rooms to mix with and return to the central corridor air. In addition, smoke tube tests detected direct air flow from the patients' rooms to the hall corridor. Perhaps the more important factor was that the patient was not diagnosed with infectious TB until after his death, by which time he had already infected 24 employees.

These earlier studies illustrate that despite the decrease in TB morbidity since the advent of anti-tuberculosis drugs in the 1940's, occupational transmission of TB continues to be a problem. In addition, while many improvements have been made in infection control procedures for TB in hospitals, evidence of occupational transmission of TB continues to be reported.

Hospitals—1985 to Present

As discussed above, the transmission of TB has been well established as an occupational hazard in the hospital setting. Many improvements were made in infection control practices. However, the resurgence in TB from 1985 to 1992 has brought to attention the fact that many TB control measures have not been implemented or have been inadequately applied. These studies demonstrate that TB continues to be an occupational hazard in the hospital setting. In addition, similar to the earlier studies, the more recent data show that the lack of early identification procedures and the lack of appropriate ventilation, performance of high-hazard procedures under uncontrolled conditions and the lack of appropriate respiratory protection have resulted in the infection of employees and in some cases the development of active disease. The more current outbreaks are even more troubling due to the emergence of multidrug-resistant forms of TB disease, which in some cases have resulted in fatality rates approaching 75%.

In a 1985 study, Chan and Tabak (Ex. 7–3) investigated the risk of TB infection among physicians in training at a Miami hospital. In this study a survey was conducted among 665 physicians in training who were in their first four years of postgraduate training. Only 404 responded to the survey, of which 13 were illegible. Another 72 were excluded because they had received the BCG vaccination. Of the remaining 319 physicians, 55 were tuberculin positive.

Of the 279 who were tuberculin negative at the beginning of their post graduate training, 15 were excluded because they had more than four years of training and 43 were excluded because they had not had repeat skin tests. Of the 221 remaining available for evaluation, 15 converted to positive tuberculin status, of which two developed active disease.

The overall conversion rate for these physicians was 6.79%. In addition, the

authors observed a positive correlation between the rate of conversion and the duration of postgraduate training. The conversion rate increased with the duration of training, beginning with a cumulative percentage of conversion of 2.06% in the first year, 8.62% in the 2nd year, 11.11% in the third year and 14.29% in the fourth year, resulting in a linear conversion rate of 3.96% per year. As noted by the authors, this linear increase suggests the hospital environment as the source of the infection. In addition, the prevalence rate of conversions in the hospital (17.24%) was much higher than would have been expected in the community for individuals of the same age.

The authors suggested that these high rates of conversion may have been a result of the fact that the hospital in this study encounters 5 to 10 times more active TB cases than most other urban hospitals. In addition, the physicians in training also are expected to be the first in line to perform physical evaluations and evaluate body fluids and secretions. While the authors did not go into detail about what, if any, TB infection control precautions were taken by these physicians in training, they did note that the evaluation of body fluids and secretions was often done in poorly ventilated and ill-equipped laboratories.

Increased rates of conversion were observed among employees in a New Orleans hospital in a 1986 study by Ktsanes et al. (Ex. 7–6). Similar to Miami, New Orleans also has a high rate of TB in the community. This study examined the skin test conversions among a cohort of 550 new employees who were followed for five years after assignment to the adult inpatient services. Of these 550 employees who were initially tuberculin negative, 17 converted to positive status over the five-year study period, resulting in an overall five-year cumulative conversion probability of 5.2%.

Regression analyses were done to examine potential contributing factors. Factors examined in the regression model included race, job, age at employment, and department. Only race (i.e., black vs. white employees) and job (i.e., nursing vs. other jobs) were found to be associated with skin test conversion. To further examine the potential job effect, conversions among blacks in nursing and blacks in other jobs were compared. Overall, the cumulative probability of converting was higher among blacks in nursing, suggesting that the acquired infections resulted from employment at the hospital rather than from the community at large. The authors thus concluded that there is an increased risk of occupational transmission of TB in TB-prevalent areas for those in close patient contact jobs.

In 1989, Haley *et al.* (Ex. 5–16) conducted a case study of a TB outbreak among emergency room personnel at a Texas hospital. In this study, a 70 year old male diagnosed with pulmonary TB and undergoing treatment was diverted, due to respiratory arrest, to Parkland Memorial Hospital while in route to another hospital. The man was admitted to the emergency room for approximately 4 hours until he was stabilized. Afterwards, the patient was placed in an intensive care unit, where he remained for 2 months until his death.

Six cases of active TB developed among emergency room employees after exposure to the TB patient, i.e., the index case. Five of these were among nurses who recalled contact with the index patient and a sixth case was an orderly who may have been infected from one of the employee TB cases. In addition, a physician exposed while administering treatment in the intensive care unit also developed active disease.

Skin test conversions were evaluated for the 153 employees of the emergency room. Of 112 previously negative employees, 16 had positive skin tests, including 5 nurses diagnosed with active TB. Fifteen of the conversions were a result of exposure to the index case. Skin tests were also evaluated for physicians in the intensive care unit. Of 21 resident physicians, two of whom had intubated the index patient, five had newly positive reactions to the tuberculin skin tests. One of the remaining three residents later developed active disease.

The authors attributed the outbreak to several factors. First, the index case had a severe case of pulmonary TB in which he produced copious amounts of sputum. Second, sixty percent of the emergency room air was recirculated without filtration adequate to remove TB bacilli, allowing for the recirculation of contaminated air. Finally, employees in the emergency room were provided surgical masks that were ineffective for protecting against transmission of airborne TB droplet nuclei. This study illustrates that the lack of effective measures for controlling TB transmission can result in the infection and development of active disease in a relatively high number of employees even after exposure to only one case of active TB.

Similarly, the lack of effective controls while performing high-hazard, cough-inducing procedures on individuals with infectious TB has also been shown to result in an increased risk of TB transmission. A 1990 report by Malasky et al. (Ex. 7–41) investigated the potential for TB transmission from high-hazard procedures by examining tuberculin skin test conversion rates among pulmonary physicians in training. In this study, questionnaires were sent annually, for 3 years, to training programs located in the top 25 cities for TB in 1983. The purpose of the study was to compare the conversion rates of pulmonary disease fellows to the conversion rates of infectious disease fellows. It was presumed that both groups have contact with patients with TB but that pulmonary disease fellows are usually more involved with invasive procedures such as bronchoscopies. Information requested on the questionnaires included the type of fellowship (i.e., pulmonary or infectious disease fellow), prior tuberculin skin test status, tuberculin status by the Mantoux technique at the end of the 3 year fellowship program, history of BCG vaccination, age, sex and ethnicity. In addition, the pulmonary disease fellows were asked to give information on the number of bronchoscopies they performed and their use of masks during the procedure.

Fourteen programs submitted data that were usable. Only programs that had both pulmonary and infectious disease fellows in the same system were used for the study. From this information, it was observed that 7 of 62 (11%) of the pulmonary fellows at risk converted their tuberculin skin test from negative to positive during the two year training period. In contrast, only 1 of 42 (2.4%) of the infectious disease fellows converted. The expected conversion rate from previous surveys was 2.3%. In addition, the pulmonary disease fellows were grouped according to tuberculin skin status. Skin test status was evaluated for its relationship to the number of bronchoscopies performed and the pattern of mask usage. No correlations were found with these factors and tuberculin skin status at the end of the fellowship. The authors suggested that the lack of correlation between mask usage during bronchoscopies and skin test conversion implies that masks worn by physicians may be inadequate. While little information was presented to evaluate this suggestion, the study does suggest that high-hazard procedures such as bronchoscopies that induce coughing, performed under uncontrolled conditions, present a risk for TB transmission.

Pearson *et al.* (1992) conducted a case-control study to investigate the factors associated with the development of MDR–TB among patients at a New

York City hospital (Ex. 5–24). As a part of this study, tuberculin skin test conversion rates were compared among health care workers assigned to wards where patients with TB were frequently admitted (e.g., HIV unit, general medical ward, respiratory therapy) or rarely admitted (operating room, orthopedic ward, outpatient clinic, psychiatry ward). In addition, infection control procedures and ventilation systems were evaluated.

Of 79 health care workers who were previously negative, 12 (15%) had newly positive skin tests. Those health care workers who were assigned to wards where patients with TB were frequently admitted were more likely to have skin test conversions (i.e., 11 of 32) than health care workers assigned to wards where patients with TB were rarely admitted (i.e., 1 of 47).

Evaluations of the infection control procedures and ventilation systems revealed that patients who were receiving isolation precautions for suspected or confirmed TB were allowed to go to common areas if they wore a surgical mask. However, many of the patients did not keep their masks on when out of their rooms. In addition, neither the isolation rooms nor rooms used for cough-inducing procedures were under negative pressure, thus allowing contaminated air to exhaust to the adjacent corridors.

Edlin *et al.* (1992) (Ex. 5–9) investigated an outbreak of MDR–TB in a New York hospital among patients with acquired immunodeficiency syndrome (AIDS). This study compared the exposure period of AIDS patients diagnosed with MDR–TB to the exposure period of AIDS patients with drug-susceptible TB. The date of diagnosis was defined as the date the sputum sample was collected from which tuberculosis bacteria were grown in culture. Patients were assumed to be infectious two weeks before and two weeks after the date of diagnosis. The period of exposure was the period in which the patient may have been infected with TB. Because of the rapid progression from infection to disease, the exposure period was defined as 6 months preceding the date of diagnosis, excluding the last two weeks.

The patients with MDR–TB were found to be more likely to have been hospitalized during their exposure periods. Those who were hospitalized were more likely to have been on the same ward and on the same day as a patient with infectious TB and were more likely to have been near a room housing an infectious patient. Examination of the infectious patients' rooms revealed that only 1 of 16 rooms had negative pressure. Based on this evidence, the authors concluded that the observed cases of MDR-TB were a likely result of infections acquired in the hospital (i.e., primary TB) rather than as a result of the reactivation of infections acquired in the past. The authors attributed these nosocomial infections to the lack of adherence to recommended infection control procedures.

While the primary focus of this study was to investigate the transmission of TB among patients, the increased likelihood of nosocomial infections among patients in the hospital would seem equally likely to apply to health care workers working in the same environment. A survey of tuberculin skin test conversions revealed an 18% conversion rate for health care workers who previously had negative skin tests and were present during this outbreak of MDR-TB. Although no statistics were reported, the authors stated that the pattern of skin test conversions suggested an ongoing risk over time rather than a recent increase during the outbreak period.

Based on an earlier 1990 report from the CDC (Ex. 5–22), Beck-Sague *et al.* 1992 (Ex. 5–21) conducted a case-control study to investigate an outbreak of MDR–TB among the staff and patients in a HIV ward and clinic of a Miami hospital. As part of the overall study the authors compared the skin test conversion rates of health care workers in the HIV ward and clinic to the skin test conversion rates of health care workers in the thoracic surgery ward where TB patients were rarely seen. In addition, the authors also evaluated the relationship between the presence of patients with infectious MDR–TB and patients with infectious drug-susceptible TB on the HIV ward and the risk of skin test conversion among the HIV ward health care workers. Infection control procedures in the HIV ward and clinic were also examined.

All patients with suspected or confirmed TB were placed in isolation. However, some patients whose complaints were not primarily pulmonary and whose chest X-rays were not highly suggestive of TB were not initially suspected of TB and were not placed in isolation. Patients who were admitted to isolation rooms were allowed to leave TB isolation 7 days after the initiation of chemotherapy regardless of clinical or bacteriologic response. Thus, in some instances, patients with MDR–TB were allowed to leave isolation while they were still infectious, before drug resistance was recognized. In addition, patients in isolation rooms sometimes left the doors open, left their rooms, and/or removed their masks while outside their rooms. Patients with TB who were readmitted to the HIV ward and who were receiving anti-TB drugs were not admitted to isolation. In some cases, these patients were later found to have infectious MDR–TB.

An environmental assessment of the ventilation revealed that among 23 rooms tested with smoke tubes, 6 had positive pressure and many of the rooms under negative pressure varied from negative to positive depending on the fan setting and whether the bathroom door was open. Aerosolized pentamidine administration rooms were also found to have positive pressure relative to adjacent treatment areas. In addition, the sputum induction rooms were found to recirculate air back to the HIV clinic.

Skin test conversions were evaluated for all health care workers (i.e., nurses and clerical staff) who tested negative on the tuberculin skin test before the outbreak period, March 1988 through April 1990. Health care workers on the HIV ward and in the HIV clinic exhibited a significantly higher rate of skin test conversion than health care workers on the thoracic surgery ward (e.g., 13/39 vs. 0/15). Ten of the conversions occurred among the 28 health care workers in the HIV ward. Among these health care workers, the authors reported a significant correlation between the risk of infection in health care workers and the number of days that patients with infectious MDR–TB were hospitalized on the HIV ward. No correlation was observed between the risk of infection among health care workers on the HIV ward and the number of days that patients with infectious drug-susceptible TB were hospitalized on the ward.

Based on skin test conversions and the evaluation of infection control practices in the HIV ward and clinic, the authors concluded that the health care workers most likely were infected by patients on the HIV ward with MDR–TB. The factors most likely contributing to this increased risk of infection included: (1) The prolonged infectiousness and greater number of days that patients with infectious MDR–TB were hospitalized, (2) the delayed recognition of TB and failure to suspect infectious TB in patients receiving what proved to be ineffective anti-TB treatment, (3) the inadequate duration of, and lapses in, isolation precautions on the HIV ward, and (4) the lack of negative pressure ventilation in isolation and treatment rooms. While the evidence in this study primarily points to the transmission of MDR–TB

from patients to health care workers, many of the problems identified with infection control procedures and ventilation would also increase the risk of acquiring drug-susceptible TB.

In addition to MDR–TB outbreak investigations in Miami, in 1993 the CDC reported an outbreak in New York City in which health care workers became infected after being exposed to patients with MDR–TB (Ex. 6–18). In this investigation, for the period December 1990 through March 1992, 32 patients were identified with MDR–TB. Twenty-eight of these patients had documented exposure to an undiagnosed infectious MDR–TB patient while all of them were in the HIV ward of the hospital.

During November 1991, health care workers who were assigned to the HIV inpatient unit and who were also previously negative on the tuberculin skin test, were given an additional skin test. Of 21 health care workers tested, 12 (57%) had converted to positive status (7 nurses, 4 aides and 1 clerical worker). None of the health care workers had used respiratory protection.

An investigation of infection control practices revealed that of 32 patients with MDR–TB, 16 were not initially suspected of TB and in these cases isolation precautions either were not used or were instituted late during the patients' hospitalization. In addition, patients who were admitted to isolation frequently left their rooms and when in their room the doors were frequently left open. Moreover, all rooms were found to be under positive pressure relative to the hall. Thus, similar to the findings in Miami, the results of this study indicate that the inability to properly isolate individuals with MDR–TB and also the use of inadequate respiratory protection may increase the risk of infection among health care workers.

Undiagnosed cases may also present a significant source for occupational transmission of TB. A case study by Cantanzaro (Ex. 5–14) described an outbreak of TB infection among hospital staff at a San Diego hospital where the hospital staff were exposed to a single patient with undiagnosed TB. In this case, a 64 year old man suffering from generalized seizures was transferred from a local jail to the emergency room and later admitted to a four bed intermediate care unit. While in the intermediate care unit he was treated with anticonvulsants but continued to have seizures accompanied with vomiting. He was therefore placed in intensive care where he underwent a variety of procedures including bronchoscopies and endotracheal intubation. During his stay, he received frequent chest therapy and suctioning. Three sputum samples were taken from the patient for smears and cultures. All AFB smears were negative. However, two cultures were positive for tuberculosis.

Despite the presence of positive cultures the patient was not diagnosed with active TB. The problem was not recognized until a physician on staff later developed symptoms of malaise and slight cough and requested a tuberculin skin test and was found to be positive. Because the physician had been tuberculin negative 8 months earlier, a contact investigation was initiated. As a part of this investigation, all employees who previously had negative tuberculin tests and who also worked in the intermediate and intensive care units where the patient had been treated were given repeat skin tests. Of 45 employees who previously had negative tuberculin skin tests, 14 (31%) converted to positive status (6 physicians, 3 nurses, 2 respiratory therapists and 1 clerk). Ten of these conversions were among the 13 previously tuberculin negative staff members who were present at the time bronchoscopies were conducted (10/13=76.9%). Four of the conversions were among 32 susceptible staff members who were not present at the bronchoscopies (4/32=12.5%). The author thus concluded that being present during the bronchoscopy of the patient was a major risk factor in acquiring the TB infection. However, the evidence did not show a significant correlation between skin test conversion and the type of exposure, i.e., close (administered direct contact) versus casual (in the room) contact. Thus, people who were present in the room during the bronchoscopy had an equal risk of infection as those administering direct patient care, presumably, as the author suggests, because droplet nuclei can disperse rapidly throughout the air of a room.

Similarly, Kantor *et al.* (Ex. 5–18) reported an outbreak of TB infection among hospital staff exposed to a single undiagnosed case of TB. The index case in this investigation was a 50 year old man who was admitted for lung cancer and was receiving chemotherapy, steroids and radiation treatment. After a month of treatment, the patient complained of a cough and chest pain and was found to have emphysema requiring additional drug treatment and a chest tube. However, even after the emphysema resolved, the patient complained of weakness, loss of appetite and fever. A sputum culture and smear were conducted for mycobacteria and found to be negative. Lung X-rays were found to be irregular but were attributed to the lung cancer. Upon his death the autopsy revealed extensive necrosis in the lung but tuberculosis was not suspected. Thus, no cultures for mycobacteria were performed and no infection control procedures were initiated. It was only upon histological examination of tissue samples one month later that the presence of TB was confirmed. Five months later one of the staff performing the autopsy developed active TB. His only history of exposure was to the index case.

As a result, a contact investigation was initiated for hospital personnel who had shared air with the patient during his stay, including the autopsy staff. Of susceptible hospital staff (i.e., those not previously found to react positive to the tuberculin skin test), infection developed in 9 of 56 (16%) exposed employees (4 autopsy staff, 4 nursing staff and 1 radiology staff). Only 3 of 333 unexposed personnel were found to have converted to positive tuberculin status at the hospital during the same period of investigation, thus indicating a 17.8 fold increase in the infection rate for the exposed group.

Undiagnosed cases of TB at time of autopsy were also indicated as the likely cause for development of active TB among staff and students in an autopsy room in a Swedish hospital (Ex. 5–19). In this study, three medical students and one autopsy technician, who were present during the autopsy of a patient with previously undiagnosed pulmonary TB, developed active TB. Both the medical students and the autopsy technician had previously received the BCG vaccine but none had any other known contact with a tuberculosis subject. Thus, it was concluded that the tuberculosis infections were most likely to have been transmitted during the autopsy. The findings of this study further illustrate the risks that undiagnosed cases of active TB present to health care workers. The lack of recognition of an active case of TB often results in a failure to initiate appropriate infection control procedures and provide appropriate personal protective equipment. In addition, this study illustrates that, while TB is most often transmitted by individuals with infectious pulmonary TB who generate droplet nuclei when they cough or speak, the autopsy procedures on deceased individuals with pulmonary TB may also aerosolize bacteria in the lungs and generate droplet nuclei.

Exposure during autopsy procedures was also suspected as a possible route of TB transmission in an upstate New

York Medical Examiner's Office (Ex. 7–152). This Medical Examiner's Office conducted autopsies on deceased inmates from upstate New York prisons. In 1991, the same year that an outbreak of MDR–TB occurred among inmates from an upstate New York prison, the Medical Examiner's office conducted autopsies on 8 inmates with TB, six of whom had infectious MDR–TB at death and who were also HIV positive and had disseminated TB disease.

Skin tests were administered to employees who had worked for at least one month during 1991 at the Medical Examiner's Office. Among 15 employees who had originally tested negative on a baseline skin test, 2 were found to have converted. These two employees worked as morgue assistants and had recent documented exposure to persons with extensive disseminated MDR–TB. No potential exposure to TB outside the Medical Examiner's Office could be found.

The autopsy area of the office had a separate ventilation system. However, air was returned to a common air plenum, allowing the air to mix between the autopsy area and other areas of the office. In addition, the autopsy room was found to be at positive pressure relative to the adjacent hallway. Employees performing or assisting at autopsies on persons known to be infected with HIV were required to wear plastic gowns, latex gloves and surgical masks. Particulate respirators were not required until November of 1991, after the installation of germicidal UV lamps. However, this was after the last MDR–TB autopsy. This study suggests that the conversion of these two morgue assistants occurred as a result of exposure to aerosolized *M. tuberculosis* resulting from autopsy procedures, either as a result of participation in an autopsy in the autopsy area or from exposure to air contaminated with aerosolized *M. tuberculosis* that was exhausted into other areas of the Medical Examiner's Office.

In addition to autopsy procedures, other procedures, such as the irrigation of abscesses at sites of extrapulmonary TB, can result in the generation of droplet nuclei. An outbreak investigation in an Arkansas hospital (Ex. 5–17) reported the transmission of TB among hospital employees exposed to a patient with a tuberculous abscess of the hip and thigh. In this study, the source case was a 67 year old man who was admitted to the hospital with a fever of unknown origin and progressive hip pain. The patient did not present any signs of pulmonary TB; however, the examination of soft tissue swelling in the hip area revealed an abscess that required drainage and irrigation. Due to the suspicion of TB, specimens for AFB smear and culture were obtained and the patient was placed in isolation. While in isolation, drainage from the abscess continued and irrigation of the abscess cavity was initiated on an 8-hour schedule. After four days, acid fast bacilli were observed in the AFB smears and TB therapy was begun. The patient remained in isolation until his death except for three days that he spent in the Intensive Care Unit (ICU) due to high fever.

An investigation of skin test surveys among the hospital employees revealed 55 skin test conversions among 442 previously nonreactive employees and 5 conversions among 50 medical students. In addition, 5 of the employees who had conversions also had active TB, including one who developed a tuberculous finger lesion at the site of a needle-stick injury incurred during the incision and drainage of the patient's abscess. All the skin test converters, except for two, recalled exposure to the source case. Of the 442 susceptible employees, 108 worked at least one day on one of the floors where the patient stayed (i.e., the surgical ward, the medical floor of the patient's room and the ICU). Four (80%) of 5 surgical suite employees who had direct contact with the patient through their assistance with the incision and irrigation of the patient's abscess had skin test conversions. In addition, 28 (85%) of 33 employees on the general medical floor and 6 (30%) of 20 ICU employees had skin test conversions. All those employees converting recalled exposure to the patient, some of whom had no direct contact with the patient.

Environmental studies revealed that two of the areas in which the patient stayed during his hospitalization did not have negative pressure. The isolation room was under positive pressure relative to adjacent rooms and the corridor. In addition, the patient's cubicle in the ICU had neutral pressure relative to the rest of the ICU. Employees in these two areas had skin test conversions even in cases where there was no direct patient contact. The lack of negative pressure was thought to have significantly contributed to the dispersion of droplet nuclei generated from the irrigation of the tuberculous abscess. In the surgical ward, air was directly exhausted to the outside. However, all employees present in the surgical ward when the patient was being treated had direct contact with the patient. There was no indication that the surgical staff had taken any special infection control precautions or had worn any personal protective equipment.

Thus, similar to other outbreak investigations, the lack of appropriate ventilation and respiratory protection stand out as the key factors in the transmission of TB to employees who are exposed to individuals with infectious TB. Moreover, this particular case study demonstrates that certain forms of extrapulmonary TB in conjunction with aerosolizing procedures, e.g., the irrigation of a tuberculous abscess, have the potential for presenting significant airborne exposures to *M. tuberculosis*.

Other aerosolizing procedures have also shown evidence of presenting airborne exposures to *M. tuberculosis*. For example, tissue processing was associated with the skin conversion of two pathologists working at a community hospital in California (Ex. 6–27). In this case study, after autopsy, a 62 year old man who had died from bronchogenic carcinoma was discovered to have a caseating lung lesion. A stain revealed a heavy concentration of acid-fast bacilli, which were identified in culture as *M. tuberculosis*. As a result, a contact investigation was initiated.

This investigation found twenty employees who had contact with the patient, including two pathologists and a laboratory assistant. All were given a tuberculin skin test and found to be negative. However, after follow-up skin testing three months later, the two pathologists had converted. Other than contact with the source case, the two had no other obvious sources of infection. One of the pathologists had been present at the autopsy. Both pathologists were present when the frozen lung sections were prepared. During this process, the lung tissue was sprayed with a compressed gas coolant, which created a heavy aerosol. Masks were not routinely worn during this tissue processing. The investigators suspected that this aerosol promoted the transmission of TB and was the likely cause of the observed infections.

While much of the health effects literature has focused on outbreaks of TB or MDR–TB, a more recent study investigated the status of infection control programs among ''non-outbreak'' hospitals (Ex. 7–147). Investigators from the Society of Health care Epidemiology of America (SHEA) and the CDC surveyed members of SHEA to assess compliance in the respondents' hospitals with the 1990 CDC Guidelines for Preventing the Transmission of TB in Health Care Facilities for the years 1989 to 1992. The survey included questions on tuberculin skin testing programs (e.g., frequency of testing,

positivity at hire, and percent newly converted), AFB isolation capabilities (e.g., negative pressure, air changes per hour, HEPA filtration) and respiratory protection.

The survey showed that of the 210 hospitals represented by the SHEA members' survey results, 193 (98%) admitted TB patients from 1989 to 1992, 40% of which had one or more patients with MDR–TB. In addition, the proportion of hospitals caring for drug susceptible TB patients rose from 88% to 92% and the proportion of hospitals caring for MDR–TB patients rose from 5% to 30%. While the number of hospitals caring for TB patients increased, the majority of those hospitals cared for a small number of patients. In 1992, approximately 89% of the hospitals reported 0 to 25 patients per year, while approximately 5% reported greater than 100 patients per year.

Few hospitals reported routine tuberculin skin testing for each of the years surveyed. For example, while 109 (52%) of the responding hospitals reported tuberculin skin test results for at least one of the years from 1989 to 1992, only 63 (30%) reported results for each of these years. When examining the conversion rates over time from 1989 to 1992, the investigators limited their analysis to the 63 hospitals reporting skin test data for each of these 4 years. Among these hospitals the median percentage of employees newly converting to positive skin test status remained constant over the 4 year period at approximately 0.34% per year (i.e., 3/1000 per year). However, when including all hospitals in the analysis, from 1989 to 1992, the number of hospitals reporting conversion rates increased from 63 to 109 and the conversion rates increased from 0.26% (i.e., 2/1000) to 0.50% (i.e., 5/1000).

With regard to AFB isolation capabilities, 62% of 181 responding hospitals reported that they had isolation facilities consistent with the 1990 CDC TB Guidelines (i.e., single-patient room, negative pressure, air directly exhausted outside, and ≥6 air changes per hour). Sixty-eight percent of the reporting hospitals had isolation facilities meeting the first three of these recommendations. For respiratory protection, the majority of health care workers in the hospitals used surgical masks. However, there was an increase in the use of dust-mist or dust-mist-fume respirators. The use of dust-mist respirators increased from 1 to 13% from 1989 to 1992 and the use of dust-mist-fume respirators increased from 0 to 10% for the same period. The only use of high efficiency particulate air (HEPA) filter respirators was by bronchoscopists and respiratory therapists at 4 hospitals.

As a second phase of this investigation, the survey responses were analyzed to determine the efficacy of the TB infection control programs among the member hospitals participating in the survey (Ex. 7–148). In this analysis, the reported conversion rates were compared to reported infection control measures (i.e., AFB isolation capabilities and respiratory protection). For purposes of comparison, hospitals were categorized as having either less than or ≥6 TB patients, less than or ≥437 beds, and admitting or not admitting MDR–TB patients.

Conversion rates were higher among health care workers from hospitals with ≥437 beds than among health care workers from smaller hospitals (0.9% vs. 0.6%, $p \leq 0.05$). This difference was more pronounced among ''higher-risk'' health care workers (i.e., health care workers including bronchoscopists and respiratory therapists). ''Higher-risk'' health care workers from hospitals with 437 or more beds had a 1.9% conversion rate compared to a conversion rate of 0.2% for ''higher-risk'' health care workers from smaller hospitals. Similarly, health care workers from hospitals where 6 or more TB patients were admitted per year had higher conversion rates than health care workers from hospitals with fewer than 6 TB patients per year (e.g., 1.2% vs. 0.6%).

For hospitals with 6 or more TB patients, conversion rates also varied depending on the level of TB infection control practices that were in place in the hospital. For example, among hospitals with 6 or more TB patients and whose AFB isolation capabilities included at least single-room occupancy, negative pressure and directly exhausted air, the conversion rates among health care workers were lower than the conversion rates among health care workers at hospitals with 6 or more TB patients but which did not have similar isolation capabilities (0.62% vs. 1.83%, $p=0.03$). For respiratory protection, however, no differences in conversion rates were observed among health care workers wearing surgical masks (0.94%) and health care workers using submicron surgical masks, dust-mist respirators or dust-mist-fume respirators (0.98%). Very few survey respondents reported use of HEPA filter respirators. For example, only four hospitals reported use of any HEPA respirators, and these were not the predominant type of respiratory protection used (Ex. 7–147). Thus, it is not possible to evaluate the efficacy of these particulate respirators in reducing conversion rates from the reported survey data.

For hospitals with fewer than 6 TB patients or with fewer than 437 beds, no differences in conversion rates were reported among health care workers from hospitals that had implemented AFB isolation capabilities such as single-room occupancy, negative pressure, or directly exhausted air and those hospitals that had not. The investigators suggested that this finding may support contentions that the efficacy of TB infection control measures vary depending on characteristics of the hospital or community exposure. However, given the small sample size of the survey, as well as the reduced potential for exposure in hospitals with fewer than 6 TB patients per year, it would be difficult to detect any differences in conversion rates among health care workers from hospitals with or without certain levels of infection control. Where more opportunity does exist for exposure (e.g., hospitals with ≥6 TB patients), this analysis does show that the implementation of TB infection control procedures can reduce the transmission of TB among health care workers.

Hospitals—Summary

In summary, the evidence clearly shows that in hospital settings, employees are at risk of occupational exposure to TB. Various studies and TB outbreak investigations have shown that employees exposed to individuals with infectious TB have converted to positive tuberculin skin status and in some cases have developed active disease. In these reports, a primary factor in the transmission of TB has been a failure to promptly identify individuals with infectious TB so that appropriate infection control measures could be initiated to prevent employee exposure. In addition, another major factor identified as contributing to occupational exposures was the lack or ineffective implementation of appropriate exposure control methods (e.g., lack of negative pressure in isolation rooms, lack of appropriate respiratory protection for exposed employees, performance of high-hazard procedures under uncontrolled conditions). The lack of early identification and appropriate control measures resulted in the exposure and subsequent infection of various hospital employees. These employees included not only health care providers administering direct patient care to individuals with infectious TB, but also hospital staff providing support services

to the infectious individuals, hospital staff working in adjacent areas of the hospital using shared air, autopsy staff and laboratory staff working with infected culture and tissue samples.

Other Occupational Settings

While hospitals have been historically recognized as the primary type of work setting where TB presents an occupational hazard, there are other work settings where the transmission of TB presents a hazard to workers. There are a variety of occupational settings in which workers can reasonably be anticipated to encounter individuals with active TB as a part of their job duties. Several work settings have been identified by the CDC where exposure to TB presents an occupational hazard: correctional facilities, long-term care facilities for the elderly, homeless shelters, drug treatment centers, emergency medical services, home-health care, and hospices. Similar to the hospital setting, these work settings have a higher number of individuals with active TB than would be expected for the general population. Many of the clients of these work settings have many characteristics (e.g., high prevalence of TB infection, high prevalence of HIV infection, intravenous drug use) that place them at an increased risk of developing active TB. These types of work settings are also similar to hospitals in that workers at these sites may also provide medical services and perform similar types of high-hazard procedures that are typically done in a hospital setting.

In addition to employees who provide medical services in these other types of work settings, there are other types of workers (e.g., guards, admissions staff, legal counsel for prisoners) who may also be exposed to individuals with infectious TB. Similar to hospitals, these work settings have an over-representation of populations at high risk for developing active TB, e.g., individuals infected with HIV, intravenous drug users, elderly individuals, and individuals with poor nutritional status and who are medically underserved. In addition to having a higher percentage of individuals with TB infection and a higher percentage of individuals at an increased risk for developing active TB, many of these work settings also share environmental factors that facilitate the transmission of TB, such as overcrowding and inadequate ventilation, which increases the occupational hazard. The following discussion describes some of the studies available in the literature that have examined the occupational transmission of TB in other occupational settings such as those listed above. Not all the settings listed by the CDC as places where TB transmission may be likely to occur have been adequately studied and thus can not be included in this discussion. However, the discussion of the following sectors clearly demonstrates that the occupational transmission of TB is not limited to the hospital setting. Occupational settings where there is an increased likelihood of exposure to aerosolized *M. tuberculosis* present the same types of occupational hazards as have been documented in the hospital setting.

Correctional Facilities

Many correctional facilities have a higher incidence of TB cases than occur in the general population. For example, the CDC reported that the incidence of TB among inmates of correctional facilities was more than three times higher than that for nonincarcerated adults aged 15–64, based on a survey of TB cases in 1984 and 1985 by 29 state health departments (Ex. 3–33). In particular, among inmates in the New York correctional system, the TB incidence increased from an annual average of 15.4 per 100,000 during 1976 to 1978 to 105.5 per 100,000 in 1986 (Ex. 7–80) to 156.2/100,000 for 1990–1991 (Ex. 7–137). Similarly, in 1987, the incidence of TB among inmates in New Jersey was 109.9 per 100,000 (approximately 11 times higher than the general population in New Jersey) and in California the incidence of TB among inmates was 80.3 per 100,000 (approximately 6 times higher than that for the general population for California) (Ex. 3–33). In 1989, the CDC reported that since 1985, eleven known outbreaks of TB have been recognized in prisons (Ex. 3–33).

The increased incidence of TB in correctional facilities has been attributed to several factors (Ex. 7–25). One, correctional facilities have a higher incidence of individuals who are at greater risk for developing active TB. For example, the population in prisons and jails may be dominated by persons from poor and minority groups, many of whom may be intravenous drug users. These particular groups may also suffer from poor nutritional status and poor health care, factors that place them at increased risk of developing active disease. Two, special types of correctional facilities, such as holding facilities associated with the Immigration and Naturalization Services, may have inmates/detainees from countries with a high incidence of TB. For foreign-born persons arriving in the U.S., the case rate of TB in 1989 was estimated to be 124 per 100,000, compared to an overall TB case rate of 9.5 per 100,000 for the U.S. (Ex. 6–26). In 1995, TB cases reported among the foreign born accounted for 35.7% of the total reported cases, marking a 63.3% increase since 1986 (Ex. 6–34). Three, many correctional facilities have a high proportion of individuals who are infected with HIV. The CDC reported that in addition to the growing increase in AIDS among prisoners, the incidence of AIDS in prisons is markedly higher than that for the U.S. general population. In 1988, the incidence of AIDS cases in the U.S. population was 13.7 per 100,000 compared to an estimated aggregate incidence for state/federal correctional systems of 75 cases per 100,000 (Ex. 3–33). Individuals who are infected with HIV or who have AIDS are at an increased risk of developing active TB due to their decreased immune capacity. The likelihood of pulmonary TB in individuals with HIV infection is reflected in the CDC's Revised Classification System for HIV infection (Ex. 6–30). In this revised classification system, the AIDS surveillance case definition was expanded to include pulmonary TB. Moreover, X-rays of individuals infected with HIV who have TB often exhibit radiographic irregularities that make the diagnosis of active TB difficult (Exs. 7–76, 7–77, 7–78, and 7–79). HIV-infected individuals may have concurrent pulmonary infections that confound the radiographic diagnosis of pulmonary TB. In addition, it may be difficult to distinguish symptoms of TB from *Pneumocystis carinii* pneumonia or other opportunistic infections. This difficulty in TB diagnosis can result in true cases of active TB going undiagnosed in this population. Undiagnosed TB has been shown to be an important cause of death in some patients with HIV infection (Ex. 7–76). Fourth, environmental conditions in correctional facilities can aid in the transmission of TB. For example, many prisons are old, have inadequate ventilation systems, and are overcrowded. In addition, inmates are frequently transferred both within and between facilities, thus increasing the potential for the spread of TB infection among inmates and staff. This increased potential for mobility among inmates also enhances the likelihood that inmates undergoing therapy for active disease will either discontinue their treatment or inadequately follow their prescribed regime of treatment. The inadequacy of their treatment may give rise not only to relapses to an infectious state of active disease, but also potentially give rise to strains of MDR–

TB. These strains of TB have a higher incidence of fatal outcome and are generally characterized by prolonged periods of infectiousness during which the risk of infection to others is increased.

The high incidence of TB among the inmate population presents an occupational hazard to the staff in these types of facilities. Recent outbreak investigations by the CDC have documented the transmission of TB to exposed workers. In an investigation of a state correctional facility in New York for 1991 (Exs. 6–3 and 7–136), eleven persons with TB were identified (10 inmates and one correctional facility guard). Nine persons (8 inmates and the guard) had MDR–TB. All eight inmates were HIV positive. The guard was HIV negative; however, he was also immunocompromised as a result of treatment for laryngeal cancer. Seven of the inmates and the guard died from MDR–TB. The eighth inmate was still alive and receiving treatment for MDR–TB 2 years after being diagnosed as having the disease. DNA analysis identified the strains of tuberculosis bacteria from these individuals to be identical.

The investigation revealed that the source case was an inmate who had been transferred from another prison where he had been previously exposed to MDR–TB. He arrived at the prison with infectious TB but refused evaluation by the infirmary staff. This inmate was placed in the general prison population where he stayed for 6 months until he was admitted to the hospital where he later died. However, before his hospitalization, he exposed two inmates living in his cell block who later developed MDR–TB. These two inmates continued to work and live in the prison until shortly before their final hospitalization. The other inmates who subsequently developed MDR–TB had several potential routes of exposure: social contact in the prison yard, contact at work sites in the prison, and contact at the prison infirmary where they shared rooms with other inmates before diagnosis with TB.

The guard who developed MDR–TB had exposure to inmates while transporting them to and from the hospital. The primary exposure for this guard apparently occurred when he was detailed outside the inmates' room during their hospitalization for MDR–TB. The inmates were hospitalized in an isolation room with negative pressure. However, upon investigation it was discovered that the ventilation system for the room had not been working correctly and had allowed air to be exhausted to the hospital corridors and other patient rooms.

A contact investigation in the prison was conducted to identify other inmates who might have been exposed during this outbreak of MDR–TB. Of those inmates with previous negative tuberculin skin tests and without active disease (306), ninety-two (30%) had documented skin test conversions. There was no tuberculin skin test program for prison staff; therefore, conversions among prison employees could not be evaluated.

The primary factors identified as contributing to this outbreak were deficiencies in identifying TB among transferred inmates, laboratory delays, and lapses in isolating inmates with active TB within the facility. Inmates with symptoms of active disease were not sent for evaluation in some cases until they became so ill they could not care for themselves. Some of these inmates were placed in the infirmary with other inmates until their diagnosis with TB. On other occasions, drug susceptibility testing was not reported until after an inmate's death, which means that appropriate patient management was not initiated.

As a result of this outbreak, a retrospective epidemiological investigation was conducted to examine the potential extent and spread of MDR–TB throughout the New York State prison system during the years 1990–1991 (Ex. 7–137). This investigation revealed that 69 cases of TB were diagnosed in 1990 and another 102 were diagnosed in 1991, resulting in a combined incidence of 156.2 cases/100,000 inmate years for 1990 and 1991 combined. Of the cases, 39 were identified as being MDR–TB, 31 of which were shown to be epidemiologically linked. Thirty-three of the individuals with MDR–TB never received any treatment for MDR–TB, 3 were diagnosed at death, and 23 died before drug susceptibility results were known. These inmates were also discovered to be highly mobile. The 39 inmates lived in 23 different prisons while they were potentially infectious. Twenty transfers were documented for 12 inmates with potentially infectious MDR–TB (9 shortly before diagnosis, one after diagnosis with TB but before diagnosis with MDR–TB, and 2 after a diagnosis of MDR–TB).

Several factors were identified as contributing to the spread of MDR–TB throughout the New York prison system: delays in identifying and isolating inmates, frequent transfers without appropriate medical evaluation, lapses in treatment, and delays in diagnosis and susceptibility testing.

A similar investigation in a California state correctional institution identified three active cases of TB (two inmates and one employee) during September and October 1991 (Ex. 6–5). As a result, an investigation was commenced to determine whether transmission of TB was ongoing in the institution. Eighteen inmates with active TB were identified. TB in 10 of these inmates was recognized for the first time while they were in the institution during 1991, resulting in an annual incidence of TB of 184 per 100,000, a rate greater than 10 times that for the state (17.4 per 100,000). Two of the 10 inmates had negative tuberculin skin tests prior to their entry into the institution. Three of the cases were determined to have been infectious during 1991.

A review of skin test data revealed that for the 2944 inmates for whom skin test results were available, 324 tested positive for the first time while in the prison system. Of these, 106 were tuberculin negative before their entry into the prison system, 96 of which occurred in the previous two years.

The employee identified as having active TB had worked as a counselor on the prison's HIV ward, where he recalled exposure to one of the 3 infectious inmates. This employee could recall no known exposures outside the prison. Similarly, two other prison employees had documented skin test conversions while working at the prison. Neither recalled exposures outside the prison; one reported exposure to an inmate with possible TB.

No information was provided in this report as to whether any isolation precautions were implemented at this facility. However, the investigators concluded that their findings suggested the likelihood that transmission of TB had occurred in the prison. Their conclusion was based on the fact that a substantial number of skin test conversions were documented among the inmates and that at least two inmates with active TB became infected while at the prison.

The transmission of TB was also reported in another California prison among prison infirmary physicians and nurses and correctional officers (Ex. 6–6). In this investigation, an inmate with active MDR–TB spent 6 months during 1990–1991 in the infirmary. The infirmary had no isolation rooms and inmates' cells were found to be under positive pressure. Employees occasionally recalled wearing surgical masks when entering the rooms of TB patients.

An analysis of available skin testing data revealed that of the 21 infirmary health care providers, only 10 had been

tested twice during the period from 1987 to 1990. Of these 10, two were newly positive, one of whom had recently converted in 1991 and had spent 5 months in the preceding year providing health care to the source case in this investigation. Another health care provider and a correctional officer who worked in the infirmary also were identified as having newly converted while at the prison. There was no yearly skin test screening, and thus their conversions could have occurred at any time between 1987 and 1991. However, 13 other inmates were diagnosed with pulmonary TB during that same period. An additional correctional officer who did not work in the infirmary also was found to have newly converted. His reported exposure occurred at a community hospital where he was assigned to an inmate with infectious TB. The officer was not provided with any respiratory protection. The lack of isolation precautions and the lack of appropriate respiratory protection suggest transmission of TB from infectious inmates in the infirmary to the prison staff, either as a result of exposure to the source case or other inmates with pulmonary TB who were also treated in the prison infirmary. Because of the lack of contact tracing or routine annual screening of inmates or staff, the full extent of transmission from the source case or other TB cases could not be determined.

Thus, similar to the evidence for the hospital setting, the evidence on correctional facilities shows that the failure to promptly identify individuals with infectious TB and provide appropriate infection control measures can result in the exposure and subsequent infection of employees with TB. These employees include the correctional facility infirmary staff, guards on duty at the facility, and guards assigned to escort inmates during transport to other facilities (e.g., outside health care facilities and other correctional facilities).

Homeless Shelters

Tuberculosis has also been recognized as a health hazard among homeless persons. The growth of the homeless population in the United States since the 1980s and the subsequent increase in the number of shelters for the homeless, furthers heightens the concern about the potential for the increased incidence and transmission of TB among the homeless, especially in crowded living conditions such as homeless shelters.

A number of factors are present in homeless shelters which increase the potential for the transmission of TB among the shelter residents and among the shelter staff. A high prevalence of TB infection and disease is common among many homeless shelters. This is not surprising, since the residents of these facilities usually come from lower socio-economic groups and often have characteristics that place them at high risk. Screening of selected clinics and shelters for the homeless has shown that the prevalence of TB infection ranges from 18 to 51% and the prevalence of clinically active disease ranges from 1.6 to 6.8% (Ex. 6–15). The CDC estimates this to be 150 to 300 times the nationwide prevalence rate (Ex. 6–17).

In addition to having a high prevalence of individuals with TB infection in the shelters, many of the shelter residents possess characteristics that impair their immunity and thus place them at a greater risk of developing active disease. For example, homeless persons generally suffer from poor nutrition, poor overall health status and poor access to health care. Many also suffer from alcoholism, drug abuse and psychological stress. Moreover, a significant portion of homeless shelter residents are infected with the HIV. In 1988, the Partnership of the Homeless Inc. conducted a survey of 45 of the nation's largest cities and estimated that there were between 5,000 and 8,000 homeless persons with AIDS in New York City and approximately 20,000 nationwide (Ex. 7–55). Due to these factors, homeless shelter residents are at increased risk of developing active disease. Thus, there is the increased likelihood that these individuals will be infectious as a result of active disease and thereby present a source of exposure for other homeless persons and for shelter employees.

In addition to having factors which increase their risk of developing active TB disease, homeless persons also are a very transient population. Because they are transient, homeless persons are more likely to discontinue or to erratically adhere to the prescribed TB therapy. Inadequately adhering to TB therapy can result in relapses to an infectious state of the disease or the development of MDR–TB. Both outcomes result in periods of infectiousness, during which they present a source of exposure to other residents and staff. In addition, environmental factors at homeless shelters, such as crowded living conditions and poor ventilation, facilitate the transmission of TB.

Outbreaks of TB among homeless shelter residents have been reported. For example, during 1990, 17 individuals with active pulmonary TB were identified among residents of homeless shelters in three Ohio cities: Cincinnati, Columbus, and Toledo (Ex. 7–51). In Cincinnati, 11 individuals with active TB were identified in a shelter for homeless adults. The index case was a man who had resided at the shelter and later died from respiratory failure. He was not diagnosed with TB until his autopsy. Of these 11 individuals, of which the index case was one, 7 were determined to be infectious. There was no indication as to whether any infection control measures were in place in the shelter. DNA analysis of 10 individual *M. tuberculosis* isolates showed identical patterns. The similarity among these DNA patterns suggested that transmission of the TB occurred in the shelter.

While the primary focus of this investigation was on the active cases reported among the residents in this Cincinnati shelter, the risk of transmission identified in this shelter also would apply to the shelter staff. Possible transmission of TB infection from the infectious individuals to the shelter staff might have been identified through tuberculin skin test conversions. However, no tuberculin skin test information for the staff was reported in this investigation.

Tuberculin skin testing results were reported in the investigation of a Columbus, Ohio shelter. In this investigation, a resident of a Columbus homeless shelter was identified with infectious pulmonary TB at the local hospital in March of 1990. The patient also had resided in a shelter in Toledo. As a result, a city-wide TB screening was initiated from April to May 1990 among the residents and staff of the city's men's shelters. Tuberculin skin tests were conducted on 363 shelter residents and 123 shelter employees. Among 81 skin-tested residents of the shelter in which the index case had resided, 32 (40%) were positive compared to 47 (22%) of 210 skin-tested residents of other shelters in Columbus who had positive skin test reactions. Similarly, among 27 employees of the shelter where the index case resided, 7 (26%) had positive skin test reactions compared to 9 (11%) of 85 employees in other men's shelters. These skin test results suggest an increased risk of transmission of TB among residents and employees of the homeless shelter where the index case resided. However, due to the lack of baseline skin test information among these residents and employees it is not possible to determine when their conversion to positive status occurred and whether this index case was their source of exposure. These results, however, do indicate a high prevalence of TB infection among homeless residents

(e.g., 40% and 22%). Many of these individuals are likely to have an increased risk of developing active TB and, as a result, they may present a source of exposure to residents and staff.

The transmission of TB has also been observed among residents and staff of several Boston homeless shelters (Exs. 7–75 and 6–25). From February 1984 through March 1985, 26 cases of TB were confirmed among homeless residents of three large shelters in Boston. Nineteen of the 26 cases occurred in 1984, thus giving an incidence of approximately 317 per 100,000, 6 times the homeless case rate of 50 per 100,000 reported for 1983 and nearly 16 times the 1984 case rate of 19 per 100,000 for the rest of Boston (Ex. 6–25).

Of the 26 cases of TB reported, 15 had MDR–TB. Phage typing of isolates from 13 of the individuals with drug-resistant TB showed identical phage types, thus suggesting a common source of exposure. As a result of this outbreak, a screening program was implemented in November 1984 over a four-night period. Of 362 people who received skin tests, 187 returned for reading, 42 (22%) were found to be positive and 3 were recent converters. Screening also was reported for the shelter staff at the three homeless facilities. At the largest of the three shelters, 17 of 85 (20%) staff members had skin test conversions. In the other two shelters, 3 of 15 (20%) and 3 of 18 (16%) staff members had skin test conversions.

Whereas MDR–TB was primarily involved in the outbreak in Boston, an outbreak of drug-susceptible TB was reported in a homeless shelter in Seattle, Washington (Ex. 7–73). From December 1986 to January 1987, seven cases of TB from homeless residents were reported to the Seattle Public Health Department. The report of 7 individuals with active TB in one month prompted an investigation, including: (1) A mass screening to detect undiagnosed cases, (2) phage typing of isolates from shelter clients to detect epidemiologically linked cases, and (3) a case-control study to investigate possible risk factors for the acquisition of TB.

A review of the case registries revealed that 9 individuals with active TB had been reported from the homeless shelter for the preceding year and four cases in the year previous to that. As a result of the mass screening in late January 1987, an additional 6 individuals with active TB were detected. Phage typing of 15 isolates from the shelter-associated cases revealed that 6 individuals with active TB diagnosed around the time of the outbreak were of the same phage type, suggesting that there was a predominant chain of infection, i.e., a single source of infection. However, there also were other phage types, suggesting several sources of infection. Therefore, the investigators suggested that there was probably a mixture of primary and reactivated cases.

In addition to the similarity of phage types among TB cases, tuberculin skin testing results suggested the ongoing transmission of TB in the shelter. For example, 10 shelter clients who were previously tuberculin negative in May 1985 were re-tested in January 1987 and 3 (30%) had converted. In addition, 43 clients who were negative in January 1987 were re-tested in June 1987 or February 1988 and 10 (23%) had converted. Factors identified as contributing to the outbreak were the increased number of men with undiagnosed infectious pulmonary TB, the close proximity of beds in the shelter, and a closed ventilation system that provided extensive recirculation of unfiltered air.

As a result of the outbreak, a control plan was implemented. This plan included repetitive mass screening, repetitive skin testing, directly observed therapy, preventive therapy and modification of the ventilation system to incorporate UV light disinfection in the ventilation duct work. After the control plan was in place, five additional individuals with active TB were observed over a 2-year follow-up period.

While the primary focus in this study was on clients of the shelter rather than the shelter staff, the risk factors present in the shelter before implementation of the control plan would have also increased the likelihood for transmission of TB to shelter employees from infectious clients.

Thus, similar to correctional facilities, homeless shelters have a number of risk factors that facilitate and promote the transmission of TB (e.g., high incidence of infected residents with an increased likelihood of developing active disease, crowded living conditions and poor ventilation). Also, similar to correctional facilities, the evidence in homeless shelters shows that the failure to promptly identify homeless residents with infectious TB and the lack of appropriate TB control measures (e.g., lack of isolation precautions or prompt transfer to facilities with adequate isolation precautions) resulted in the transmission of TB to shelter employees.

Long-Term Care Facilities for the Elderly

Long-term care facilities for the elderly also represent a high-risk population for the transmission of TB. TB disease in persons over the age of 65 constitutes a large proportion of TB in the United States. Many of these individuals were infected in the past, before the introduction of anti-TB drugs and TB control programs when the prevalence of TB disease was much greater among the general population, and have harbored latent infection over their lifetimes. However, with advancing age, these individuals' immune function starts to decline, placing them at increased risk of developing active TB disease. In addition, they may have underlying disease or overall poor health status. Moreover, residents are often clustered together and group activities are often encouraged. TB case rates are higher for this age group than for any other. For example, the CDC reports that in 1987, the 6,150 cases of TB disease reported for persons ≥65 years of age accounted for 27% of the U.S. TB morbidity although this group only represented 12% of the U.S. population (Ex. 6–14).

Because of the higher prevalence of TB cases among this age group, employees of facilities that provide long-term care for the elderly are at increased risk for the transmission of TB. More elderly persons live in nursing homes than in any other type of residential institution. The CDC's National Center for Health Statistics reports that elderly persons represent 88% of the nation's approximately 1.7 million nursing home residents. As noted by the CDC, the concentration of such high-risk individuals in long-term care facilities creates a high-risk situation for the transmission of TB (Ex. 6–14).

In addition to having a higher prevalence of active TB, the recognition of TB in elderly individuals may be difficult or delayed because of the atypical radiographic appearance that TB may have in elderly persons (Exs. 7–59, 7–81, 7–82, and 7–83). In this situation, individuals with active TB may go undiagnosed, providing a source of exposure to residents and staff.

While the increased incidence of TB cases among the elderly in long-term care facilities may be a result of the activation of latent TB infections, the transmission of TB infection to residents and staff from infectious cases in the facilities has been observed and reported in the scientific literature.

For example, Stead *et al.* (1985) examined the reactivity to the tuberculin skin test among nursing home residents in Arkansas (Ex. 7–59). This study involved a cross-sectional survey in which tuberculin skin tests were given to all current nursing home

residents. In addition, all newly-admitted nursing home residents were skin tested. For the three year period evaluated, 25,637 residents of the 223 nursing homes in Arkansas were tested.

Of 12,196 residents who were tested within one month of entry, only 12 percent were tuberculin positive, including those for whom a booster effect was detected. However, among the 13,441 residents for whom the first test was delayed for more than a month, 20.8% were positive. In addition, the results of retesting 9,937 persons who were tuberculin negative showed an annual conversion rate of approximately 5% in nursing homes in which an infectious TB case had been recognized in the last three years. In nursing homes with no recognized cases, the authors reported an annual conversion rate of approximately 3.5%. The authors concluded that their data supported the contention that tuberculosis may be a rather common nosocomial infection in nursing homes and that new infections with tuberculosis is an important risk for nursing home residents and staff.

Brennen *et al.* (Ex. 5–12) described an outbreak of TB that occurred in a chronic care Veteran's Administration Medical Center in Pittsburgh. This investigation was initiated as a result of two skin test conversions identified through the employee testing program. One converter was a nurse working on ward 1B (a locked ward for neuropsychiatric patients) and the other was a physician working in an adjacent ward, 1U, who also had significant exposure to ward 1B. The source of infection in this investigation was traced to two patients who had resided on ward 1B and who had either a delayed or undiagnosed case of TB. The contact investigation revealed 8 additional conversions among patients, 4 in ward 1B and 4 in wards 2B and 4B (units on the floor above 1B).

Because the source cases were initially unidentified, no isolation precautions were taken. Smoke tracer studies revealed that air discharged from the window air conditioning unit of one of the source patients discharged directly into the courtyard. Air from this courtyard was the air intake source for window air conditioning units in the converters' room on ward 2B and thus was one of the possible sources of exposure.

In addition to the contact investigation on ward 1B and the adjacent units, hospital-wide skin testing results were evaluated. Of 395 employees tested, 110 (28%) were positive. The prevalence in the surrounding community was estimated to be 8.8%. Of those employees initially negative, 38 (12%) converted to positive status. Included among these were employees in nursing (18), medical (3), dental (1), maintenance/engineering (3), supply (1), dietary (9), and clerical (2) services.

Occupational transmission of TB was also reported in a nursing home in Oklahoma (Ex. 6–28). In August 1978, a 68 year old female residing in the east wing of the home was diagnosed with pulmonary TB. She was subsequently hospitalized. However, by that time she had already had frequent contact with other residents in the east wing. As a result, a contact investigation, in which all residents of the home were given skin tests, was initiated.

The investigation revealed that the reaction rate for residents in the east wing (34/48, 71%) was significantly higher than the reaction rates of residents living in the north and front wings (30/87, 34%). No baseline skin test information was presented for the residents to determine the level of conversion. However, it was noted that half of the nursing home residents were former residents of a state institution for the developmentally disabled. A 1970 tuberculin skin test survey of that institution had shown a low rate of positive reactions.

In addition to the nursing home residents, nursing home employees were also skin tested. Of the 91 employees tested, 61 (67%) were negative and 30 (33%) were positive. Similar to results observed among the residents, positive reaction rates were higher for employees who had ever worked in the east wing (50%) than for those who had never worked in the east wing (23%). Retesting of the employees 3 months later revealed 3 conversions. These results suggested that there may have been occupational transmission of TB in this facility.

Occupational transmission has also been observed in a retrospective study of residents and employees who lived or worked in an Arkansas nursing home between 1972 and 1981 (Ex. 7-83). In this retrospective study, investigators reviewed the skin testing and medical chart data collected over a 10-year period at an Arkansas nursing home. Among the nursing home residents who were admitted between 1972 and 1982, 32 of 226 residents (17%) who were initially tuberculin negative upon admittance became infected while in the home, based on conversion to positive after at least two previous negative tests. Twenty-four (63%) of these conversions were infected in 1975, following exposure to one infectious resident. This resident, who had negative skin tests on three previous occasions during his stay in the home, was not diagnosed with TB until after he was hospitalized because of fever, loss of weight and productive cough. The remaining 37% converted in the absence of a known infectious case. Thus, the authors suggested that nosocomial infections are likely to result from persons unsuspected of having TB.

Skin testing was also reviewed for employees of the nursing home. Questionnaires were completed by 108 full-time employees. Eleven of 68 employees with follow-up skin tests converted to positive skin status during the study period. Ten of the 11 (91%) converters reported that they had been in the nursing home in 1975, the same year in which many of the residents were also found to have converted from a single infectious case. In addition, employees working at least 10 years in the home had a higher percentage of conversions (9 of 22, 40%) than employees working less than 10 years (2 of 46, 4.4%). Based on the results of this study, the authors concluded that, in addition to occurrence of TB cases from the reactivation of latent infections among the elderly, TB can also be transmitted from one resident to another resident or staff. Consequently, TB must be considered as a potential nosocomial infection in nursing homes.

Thus, long-term care facilities for the elderly represent a high-risk situation for the transmission of TB. These types of facilities possess a number of characteristics that increase the likelihood that active disease may be present among the facility residents and may go undetected. Similar to other high-risk settings, the evidence shows that the primary factors in the transmission of TB among residents and staff have been the failure to promptly identify residents with infectious TB and initiate and adequately implement appropriate exposure control measures.

Drug Treatment Centers

Another occupational setting that has been identified as a high-risk environment for the transmission of TB is drug treatment centers. Similar to other high-risk sites, drug treatment centers have a higher prevalence of TB infection than the general population. For example, in 1989 the CDC funded 25 state and city health departments to support tuberculin testing and administration of preventive therapy in conjunction with HIV counseling and testing. In this project, 28,586 clients from 114 drug treatment centers were given tuberculin skin tests. Of those, 2,645 (9.7%) were positive (Ex. 6–8). When persons with previously

documented positive tests were included, 4167 (13.3%) were positive.

There is also evidence to suggest that drug dependence is a risk factor for TB disease. For example, Reichman et al. (Ex. 7–85) evaluated the prevalence of TB disease among different drug-dependent populations in New York: (1) An in-hospital population, (2) a population in a local drug treatment center, and (3) a city-wide population in methadone clinics. For the in-hospital population of 1,283 patients discharged with drug dependence, 48 (3.74%) had active disease, for a prevalence rate of 3,740 per 100,000. In comparison, the TB prevalence rate for the total inpatient population was 584 per 100,000 and for New York City as a whole was 86.7 per 100,000. Screening of clients at a local drug treatment center in Harlem revealed a TB prevalence of 3750 per 100,000 in the drug-dependent population. Similarly, in the New York methadone program, the city-wide TB prevalence was 1,372 per 100,000. The authors also reported that although estimates of TB infection rates for both drug-dependent and non-drug dependent people were similar, the prevalence of TB disease among the drug-dependent was higher, thus suggesting that drug dependency may be a risk factor for disease.

Clients of drug treatment centers not only have a high prevalence of TB infection, a majority of them are intravenous drug users. Of the estimated 645,000 clients discharged each year from drug treatment centers, approximately 265,000 are intravenous drug users who either have or are at risk for HIV infection. In the Northeastern U.S., HIV seroprevalence rates of up to 49% have been reported (Ex. 6–8). These individuals are at increased risk of developing active TB disease.

To determine the risk of active TB associated with HIV infection, Selwyn *et al.* (Ex. 5–6) prospectively studied 520 intravenous drug users enrolled in a methadone maintenance program. In this study, 217 HIV seropositive and 303 seronegative intravenous drug users, who had complete medical records documenting their history of TB and skin test status, were followed from June 1985 to January 1988. On admission to the methadone program, and at yearly intervals, all patients were given tuberculin skin tests.

Forty-nine (23%) of the seropositive patients and 62 (20%) of the seronegative patients had positive reactions to the skin test before entry into the study. Among the patients who initially had negative skin tests, 15 of 131 (11%) seropositive patients and 62 of 303 (13%) seronegative patients converted to positive tuberculin status. While the prevalence and incidence rates of TB infection were similar for the two groups of patients, seropositive patients showed a higher incidence of developing active disease. Active TB developed in 8 of the seropositive subjects with TB infection (4%), whereas none of the seronegative patients with TB infection developed active TB during the study period.

Among individuals who are infected with HIV or who have AIDS, TB disease may be difficult to diagnosis because of the atypical radiographic appearance that TB may present in these individuals. In these individuals, TB may go undiagnosed and present an unsuspected source of exposure. Clients of drug treatment centers also may be more likely to discontinue or inadequately adhere to TB therapy regimens in instances where they develop active disease. As in other instances, this increases the likelihood of relapse to active disease or possibly the development of MDR–TB, both of which result in additional or even prolonged periods of infectiousness during which other clients or staff can be exposed.

There is evidence showing the transmission of TB in drug treatment facilities among both the clients and the staff. In a CDC case study (Ex. 5–6), a Michigan man who was living in a residential substance abuse treatment facility and was undergoing therapy for a previously diagnosed case of TB disease, was discovered by the local health department to have MDR–TB. As a result, a contact investigation was initiated at the drug treatment facility in which he resided.

Of the 160 clients and staff who were identified as potential contacts, 146 were tested and given tuberculin skin tests in November. No health screening program had been in place at the facility. The following March repeat skin tests were given. Of the 70 persons who were initially tuberculin negative and were still present in the facility, 15 (21%) had converted to positive status (14 clients and 1 staff member). The investigators noted that the number of converters may have been underestimated for two reasons. Many of the clients were at risk for HIV infection and thus may have been anergic and not responded to the tuberculin skin tests. In addition, nearly half of the clients who were initially negative were not available for repeat skin testing.

Several factors may have contributed to the observed conversions in this facility. For example, no health screening program was in place. Therefore, individuals with TB would go unidentified. In addition, the clients were housed in a building with crowded dormitories for sleeping. The only ventilation in this building was provided by opening windows and doors. Thus, environmental conditions were ideal for the transmission of TB.

Consequently, the high-risk characteristics of clients who frequent these centers (e.g., high prevalence of infection and factors increasing the likelihood of developing active disease) and environmental characteristics of the center (e.g., crowding and poor ventilation), lead to drug treatment centers being considered a high-risk setting for the transmission of TB. The available evidence shows that the failure to promptly identify clients with infectious TB and to initiate and properly implement exposure control methods (e.g., proper ventilation) resulted in the infection of clients and staff at these facilities.

Conclusion

The available evidence clearly demonstrates that the transmission of TB represents an occupational hazard in work settings where employees can reasonably be anticipated to have contact with individuals with infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* as a part of their job duties. Epidemiological studies, case reports, and outbreak investigations have shown that in various work settings where there has been an increased likelihood of encountering individuals with active TB or where high-hazard procedures are performed, employees have become infected with TB and in some cases developed active disease. While some infections were a result of more direct and more prolonged exposures, other infections resulted from non-direct and brief or intermittent exposures. Because of the variability in the infectiousness of individuals with active TB, one exposure may be sufficient to initiate infection.

Several factors, common to many of these work settings, were identified as contributing to the transmission of TB: (1) Failure or delayed recognition of individuals with active TB within the facility, and (2) failure to initiate or adequately implement appropriate infection control measures (e.g., performance of high-hazard procedures under uncontrolled conditions, lack of negative pressure ventilation, recirculation of unfiltered air, and lack of appropriate respiratory protection). Thus, in work settings where employees can reasonably be anticipated to have contact with individuals with infectious

TB or air that may contain aerosolized *M. tuberculosis* and where appropriate infection control programs are not in place, employees are at increased risk of becoming infected with TB.

Infection with TB is a material impairment of the worker's health. Even though not all infections progress to active disease, infection marks a significant change in an individual's health status. Once infected, the individual is infected for his or her entire life and carries a lifetime risk of developing active disease, a risk they would not have had they not been infected. In addition, many individuals with infection undergo preventive therapy to stop the progression of infection to active disease. Preventive therapy consists of very toxic drugs that can cause serious adverse health effects and, in some cases, may be fatal.

Although treatable, active disease is also a serious adverse health effect. Some TB cases, even though cured, may result in long-term damage to the organ that is infected. Individuals with active disease may need to be hospitalized while they are infectious and they must take toxic drugs to stop the progressive destruction of the infected tissue. These drugs, as noted above, are toxic and may have serious side effects. Moreover, even with advancements in treating TB, individuals still die from TB disease. This problem is compounded by the emergence of multidrug-resistant strains of TB. In these cases, due to the inability to find adequate drug regimens which can treat the disease, individuals remain infectious longer, allowing the disease to progress further and cause more progressive destruction of the infected tissue. This increases the likelihood of long-term damage and death.

V. Preliminary Risk Assessment for Occupational Exposure to Tuberculosis

Introduction

The United States Supreme Court, in the ''benzene'' decision (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980)), has stated the OSH Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant health risk under existing conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that

> ''before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' (448 U.S. 642).

The Court in the Cotton Dust case (*American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA health standards. However, the Court reaffirmed its previous position in the ''benzene'' case that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible. The following paragraphs present an overall description of OSHA's preliminary quantitative risk assessment for occupational exposure to tuberculosis (TB).

An earlier version of this risk assessment was reviewed by a group of four experts in the fields of TB epidemiology and mathematical modeling. The reviewers were George Comstock, MD, MPH, DPH, Alumni Centennial Professor of Epidemiology, The Johns Hopkins University; Neil Graham MBBS, MD, MPH, Associate Professor of Epidemiology, The Johns Hopkins University; Bahjat Qaqish, MD, PhD, Assistant Professor of Biostatistics, University of North Carolina; and Patricia M. Simone, MD, Chief, Program Services Branch, Division of Tuberculosis Elimination, CDC. The reader is referred to the peer review report in the docket for additional details (Ex. 7–911). The revised version of OSHA's risk assessment, as published in this proposed rule, includes OSHA's response to the reviewers' comments as well as updated risk estimates based on recent purified protein derivative (PPD) skin testing data made available to the Agency since the peer review was performed and is generally supported by the reviewers or is consistent with reviewers' comments. (Note: PPD skin test and tuberculin skin test (TST) are synonymous terms.)

The CDC estimates that, once infected with *M. tuberculosis*, an untreated individual has a 10% lifetime probability of developing active TB and that approximately half of those cases will develop within the first or second year after infection occurs. Individuals with active TB represent a pool from which the disease may spread. Based on data from the CDC, OSHA estimates that every index case (i.e., a person with infectious TB) results in at least 2 other infections (Ex. 7–269). For some percentage of active cases, a more severe clinical course can develop which can be attributed to various factors such as the presence of MDR–TB, an allergic response to treatment, or the synergistic effects of other health conditions an individual might have. Further, OSHA estimates that for 7.78% of active TB cases, TB is expected to be the cause of death. Section 6(b)(5) of the OSH Act states 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 material 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.

For this rulemaking, OSHA defines TB infection as a ''material impairment of health'', for several reasons. First, once infected with TB, an individual has a 10% lifetime likelihood of developing active disease and approximately 1% likelihood of developing more serious complications leading to death. Second, allergic reaction and hepatic toxicity due to chemoprophylaxis with isoniazid, which is one of the drugs used in the recommended course of preventive treatment, pose a serious threat to a large number of workers. Third, defining infection with *M. tuberculosis* as material impairment of health is consistent with OSHA's position in the Bloodborne Pathogens standard and is supported by CDC and several stakeholders who participated in the pre-proposal meetings, as well as Dr. Neil Graham, one of the peer reviewers of this risk assessment. In his comments to OSHA, Dr. Graham stated,

> The focus of OSHA on risk of TB infection rather than TB disease is appropriate. TB infection is a potentially adverse event, particularly if exposure is from a MDR–TB patient, or if the health-care or institutional worker is HIV seropositive. In addition, a skin test conversion will in most cases mandate use of chemoprophylaxis for >6 months which is at least inconvenient and at worst may involve adverse drug reactions. (Ex. 7–271)

The approach taken in this risk assessment is similar to the approach OSHA took in its risk assessment for the Bloodborne Pathogens standard. As with bloodborne pathogens, the health response (i.e., infection) associated with exposure to the pathogenic agent does not depend on a cumulative level of exposure; instead, it is a function of intensity and frequency of each

exposure incident. However, unlike hepatitis B, where the likelihood of infection once an exposure incident occurs is known with some degree of certainty, the likelihood of becoming infected with TB after an exposure incident is not as well characterized. With TB, the likelihood of infection depends on the potency of an exposure incident and the susceptibility of the exposed individual (which is a function of the person's natural resistance to TB and his or her health status). Further, the potency of a given exposure incident is highly dependent on several factors, such as the concentration of droplet nuclei in the air, the duration of exposure, and the virulence of the pathogen (e.g., pulmonary and laryngeal TB are considered more infectious than other types).

The Agency has sufficient data to quantify the risk associated with occupational exposure to TB among health care workers in hospitals on a state-by-state basis. In addition to hospital employee data, OSHA has obtained data on selected health care employee groups from the TB Control Office of the Washington State Health Department. These groups include workers employed in long-term health care, home health care, and home care. Small entities are encouraged to comment and submit any data or studies on TB infection rates relevant to their business.

Because it is exposure to aerosolized *M. tuberculosis* that places workers at risk of infection, and not some factor unique to the health care profession, the Agency concluded that the experience of these groups of health care workers is representative of that of the other ''high-risk'' workers covered by this proposal. This means that the risk estimates calculated for these groups of workers are appropriate to use as the basis for describing the potential range of risks for workers in other work settings where workers can be expected to come into close and frequent contact with individuals with infectious TB (or with other sources of aerosolized *M. tuberculosis*) as an integral part of their job duties. As discussed in section IV (Health Effects), epidemiological studies, case reports, and outbreak investigations have shown that workers in various work settings, including but not limited to hospitals, have become infected with tuberculosis as a result of occupational exposure to aerosolized *M. tuberculosis* when appropriate infection control programs for tuberculosis were not in place.

In this preliminary risk assessment, OSHA presents risk estimates for TB infections, cases of active disease, and TB-related deaths (i.e., where TB is considered the cause or a major contributing cause of death) for workers with occupational exposure to tuberculosis.

A number of epidemiological studies demonstrate an increased risk of TB infection among health care workers in hospitals and other work settings. A brief review of a selection of these studies is presented below, followed by OSHA's estimates of excess risk due to occupational exposure. Finally, OSHA presents a qualitative assessment of the risk of TB infection caused by occupational exposure to tuberculosis in correctional facilities, homeless shelters, drug treatment centers, medical laboratories, and other high-risk work groups.

Review of the Epidemiology of TB Infection in Exposed Workers

There are several studies in the published scientific literature demonstrating the occupational transmission of infectious TB. Reports of TB outbreaks and epidemiologic surveillance studies have shown that health care and certain other workers are, as a result of their job duties, at significantly higher risk of becoming infected than the average person.

OSHA conducted a thorough search of the published literature and reviewed all studies addressing occupational exposure to tuberculosis and TB infection in hospitals and other work settings. All published studies show positive results (i.e., workers exposed to infectious individuals have a high likelihood of becoming infected with TB). Because there are so many studies, OSHA selected a representative subset of the more recent studies conducted in the U.S. to include in this section. These studies were chosen because they show occupational exposure in various work settings, under various working conditions, and under various scientific study designs.

OSHA's summary of the studies is presented in Table V–1(a) and Table V–1(b). These studies represent a wide range of occupational settings in hospitals, ranging from TB and HIV wards in high prevalence areas, such as New York City and Miami, to hospitals with no known TB patients located in low prevalence areas such as the state of Washington. The studies include prospective studies of entire hospitals or groups of hospitals, retrospective surveys of well-controlled clinical environments, such as an HIV ward in a hospital, and case studies of single-source infection (i.e., outbreak investigations).

TABLE V–1(A).—OUTBREAK INVESTIGATIONS OF TB INFECTION

Authors/year	Setting/source	Risk of TB in health care workers	Contributing factors
Catanzaro (1982)	Hospital intensive care unit/San Diego/1 index case—7-day hospital stay.	14/45 (31%) PPD conversions, 10/13 (77%) PPD conversions among health care workers present at bronchoscopy.	Poor ventilation. No report on respirator use.
Kantor et al. (1988)	VA hospital in Chicago autopsy room/1 index case undiagnosed until histology exam of autopsy tissue.	9/56 (16%) PPD conversions among exposed workers vs. 3/333 (1%) conversions among unexposed (RR=17.8) 3 workers developed active TB.	No mechanical ventilation on medical ward (autopsy room): no isolation. Autopsy room had 11 air changes/hour and no air recirculation.
Beck-Sague (1992)	Jackson Memorial Hospital in Miami MDR–TB in HIV/patients on HIV ward and clinic during 1989–91.	13/39 (33%) PPD conversions on HIV ward and clinic.	Some rooms had positive pressure. Inadequate triage of patients with suspected TB. Delay in use of isolation. Early discharge from isolation.

TABLE V–1(B).—SURVEILLANCE STUDIES OF TB INFECTION IN EXPOSED HEALTH CARE WORKERS

Authors/year	Setting/source	Study period	Population	Risk of TB in health care workers	Comments
Price et al. (1987)	19 Eastern North Carolina hospitals.	1980–84	All Hospital workers	1.80% annual PPD conversion rate.	
	29 Central North Carolina hospitals.	.....	.....	0.70% annual PPD conversion rate.	
	8 Western North Carolina hospitals.	.....	.....	0.61% annual PPD conversion rate.	
Aitken et al. (1987)	64 hospitals in Washington State.	1982–84	All Hospital workers	0.1% PPD conversion rate/in 3 years.	Strict adherence to CDC guidelines.
Malasky et al. (1990)	14 urban hospitals in U.S	([1])	Physicians in training in pulmonary medicine and infectious disease.	11% PPD conversion/3 years among pulmonary fellows, 2.4% PPD conversions/3 years among infectious disease fellows.	
Dooley et al. (1992)	Hospital in Puerto Rico TB in HIV-infected patients.	1989–90	Hospital workers (n=908)	Prevalence study: 54/109 (50%) nurses exposed to TB patients had positive PPDs 35/188 (19%) clerical workers with no exposure to TB had positive PPDs (p<0.001).	Isolation rooms did not have negative pressure. Recirculated air was not filtered.
NIOSH	Jackson Memorial Hospital, Miami.	1989–92	Hospital workers in selected wards (n=607).	60% annual PPD conversion among 263 exposed workers, 0.6% annual PPD conversion among 344 unexposed workers.	Incomplete isolation facilities. Improper application of isolation procedures.
Cocchiarella et al. (1996).	Cook County Hospital, Chicago.	1991	Graduating physicians with at least 1 year of clinical work at CCH (n=128).	18.8% 3-year PPD conversion rate for house staff in internal medicine vs. 2.2% PPD conversion rate for house staff in other specialties.	Residents were offered limited respiratory protection during exposures. No protocol available for early identification of suspect TB cases. PPD testing program incomplete. Inadequate isolation facilities.

[1] Mid 1980's (3 years).

Outbreak investigations describe occupational exposure to tuberculosis from single index patients or a well-defined group of patients. Such investigations are more likely to demonstrate an upper limit of occupational risk in different settings, usually under conditions of suboptimal environmental and infection controls. Although outbreak investigations demonstrate the existence of occupational risk under certain conditions and the importance of the early identification of suspect TB patients quite well, these studies do not provide information conducive to risk assessment estimations. Limitations of outbreak investigations include the frequent absence of baseline PPD test results, the difficulty of extrapolating the results to non-outbreak conditions of TB exposure, and, often, small sample sizes. Table V–1(a) lists some of the published outbreak investigations and shows the risks posed to health care workers by such outbreaks, as well as the failures in control programs contributing to these episodes.

Prospective and/or retrospective surveillance studies are used to estimate conversion rates from negative to positive in PPD skin testing programs. These conversion rates can be used to estimate the excess incidence of TB infection. Surveillance studies among health care workers lend themselves to a more systematic evaluation of the risk of TB infection than outbreak investigations, for several reasons. First, these studies better reflect the risk of TB experienced by workers under routine conditions of exposure. Second, these studies are usually based on a larger group of workers and therefore yield more precise and accurate estimates of the actual risk of infection. However, the extent to which results from surveillance studies can be generalized depends on a careful evaluation of the study population. Some studies report skin test conversion rates for all workers in the hospital(s) under study. Such studies often include large groups of employees with little or no exposure to TB. Results from such studies may reflect an overall estimate of risk in that environment, but may underestimate the occupational risk of those with frequent exposure.

Other surveillance studies report PPD conversion rates of more narrowly-defined groups of workers, usually those working in ''high-risk'' areas within a hospital such as the HIV or TB wards. Some of these studies have internal control groups (i.e., they compare PPD conversion rates between a group of workers with extensive exposure to TB and a group of workers with minimal or no exposure to TB), thus making it possible to more precisely quantify the magnitude of excess risk due to occupational exposure. However, these studies are also limited in their usefulness for risk assessment purposes. They usually have small sample sizes, making it more difficult to observe statistically significant differences. More

importantly, internal control groups may overestimate background risk, and thus underestimate excess occupational risk, unless painstaking efforts are made to eliminate from the control group those individuals with the potential for occupational exposure, a difficult task in some hospital environments. Table V–1(b) contains a selected list of published surveillance studies.

In reviewing Table V–1(a) and Table V–1(b), the reader should bear in mind that these tables are not intended to present an exhaustive list of epidemiologic studies with TB conversion rates in occupational settings. Instead, these tables present brief summaries of some of the epidemiologic evidence of occupational TB transmission found in the published literature; they are intended to convey the seriousness of the risk posed to health care workers and to illustrate how failures in control programs contribute to this risk. Upon reviewing these studies, a consistent pattern emerges: these work settings are associated with a high likelihood for occupational exposure to tuberculosis, and high rates of TB infection are being observed among health care workers.

Quantitative Assessment of Risk

Data availability usually dictates the direction and analytical approach OSHA's risk assessment can take. For this rulemaking, three health endpoints will be used: (1) TB infection, which is ''material impairment of health'' for this proposed standard; (2) Active disease following infection; and, (3) Risk of death from active TB.

In order to account for regional variability in TB prevalence and therefore to account for expected variability in the risk of TB infection in different areas, the Agency chose to develop occupational risk estimates on a state-by-state basis. This approach was criticized by Dr. Neil Graham as being too broad and ''* * * insufficient in light of the tremendous variability * * * that can occur within a state.'' (Ex. 7–911). The Agency recognizes that risk estimates on a county-by-county basis would be preferable; however, the unavailability of comprehensive county data has prevented the Agency from conducting such analysis.

The annual excess risk of TB infection due to occupational exposure is defined as a multiplicative function of the background rate of infection and is expressed as:

$p = ERR_o * R_b$

where:

p is the annual excess risk due to occupational exposure,

R_b is the background rate of TB infection, and

ERR_o is a multiplicative factor denoting the excess relative risk due to occupational exposure (ERR_o).

Estimates of ERR_o are derived from surveillance studies of workers with occupational exposure to TB. ERR_o is defined as the relative difference between the overall exposed worker risk and the background (population) risk and is calculated as the difference between overall worker and background risk divided by the background risk.

The annual excess risk due to occupational exposure is defined as a function of the background risk because of data limitations. If data on overall worker risk were available for each state, then the excess risk due to occupational exposure would simply be the difference between overall worker risk and background risk. Instead, the annual excess risk due to occupational exposure (i.e., p) is estimated using a multiplicative model because data on overall worker risk (i.e., R_w) were available only for the states of Washington, and North Carolina and for Jackson Memorial Hospital located in Miami, Florida. Therefore, the annual excess risk due to occupational exposure in state i (p_i) is expressed as:

$$p_i = \frac{\left(R_{wj} - R_{bj}\right)}{R_{bj}} * R_{bi}$$

where:

R_{wj} is the overall worker risk estimated from surveillance studies (study j),

R_{bj} is the study control group risk (i.e., study background risk), and

R_{bi} is the background rate for state i.

When i=j (i.e., Washington State or North Carolina), the excess risk due to occupational exposure, is expressed as the straight difference between overall worker risk and background risk.

OSHA calculated estimates of ERR_o based on three occupational studies: the Washington State study, the North Carolina study, and the Jackson Memorial Hospital study (Exs. 7–263, 7–7, 7–108). These estimates were expressed as percent change above each study's background. The derivation of these estimates is described in section 2.

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., OSHA: (1) Estimated background TB infection rates by state (R_{bi}), and (2) applied estimates of ERR_o, derived from the occupational studies, to the state background rates to calculate estimates of excess risk due to occupational exposure by state.

OSHA used a multiplicative function of each state's background infection rate to estimate excess risk of TB infection because the probability of occupational infection can be viewed as a function of the number of contacts and frequency of contacts with infectious individuals. Thus, estimates of expected relative increase in risk above background due to occupational exposure are calculated for the three available studies and these relative increases (i.e. ERR_o) are multiplied by background rates for each state to derive estimates of excess occupational risk by state. These state estimates are then used to derive a national estimate of occupational risk.

The CDC compiles and publishes national statistics on the incidence of active TB in the U.S. by state based on reported cases. OSHA relied on these data to estimate TB infection background rates through the use of a mathematical model because information on TB infection is not being collected nationwide by CDC. A more detailed discussion on the methodology and derivation of background risk estimates by state is found in section 3, and discussion on the estimation of occupational risk estimates by state is found in section 4 of this risk assessment.

Because section 6(b)(5) of the OSH Act requires OSHA to assess lifetime risks, OSHA has converted the annual excess risk due to occupational exposure into an excess lifetime risk based on a 45-year working lifetime. The formula used to calculate lifetime occupational risk estimates of the probability of at least one occurrence of TB infection due to occupational exposure in 45 years is expressed as $\{1-(1-p)^{45}\}$, where p is the annual excess risk due to occupational exposure. Two assumptions are critical in defining lifetime risk: (1) the exposure period is 45 years, and (2) the annual excess risk remains constant. The implication of the second assumption is that the worker's exposure profile and working conditions, which may affect the level and intensity of exposure, and the virulence of the pathogen, remain unchanged throughout a working lifetime. The merit of this assumption was questioned by Dr. Graham, because, as he states ''* * * patient contact may vary greatly throughout a career for many HCWs [health care workers].'' and '' * * * physicians (and nurses) often do not have extensive patient contact until [their] mid-twenties, while other workers increasingly retire early.'' Dr. Graham recommends that OSHA's risk assessment be adjusted to account for variable exposure levels and variable working lifetimes. Although accounting

for variable exposure levels could result in more precise risk estimates, the unavailability of comprehensive information on lifetime TB exposure scenarios by occupational group prevented the Agency from developing a more complex risk model.

OSHA has customarily assumed a 45 year working lifetime in setting health standards. The Agency believes that this assumption is reasonable and consistent with the Act. The Act requires the Secretary to set a standard for toxic substances that would assure ''no employee * * * suffer material impairment of health or functional capacity *even if such employee has regular exposures to the hazard for the period of his working lifetime.*'' 29 U.S.C. § 655(b)(5) (emphasis added). The U.S. Court of Appeals for the District of Columbia upheld the use of a 45-year lifetime in the asbestos standard against an assertion by the Asbestos Information Association that the average duration of employment was five years. *Building and Construction Trades Department, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1264, 1265 (D.C. Cir. 1988). The Court said that OSHA's assumption ''appears to conform to the intent of Congress'' as the standard must protect even the rare employee who would have 45 years of exposure. *Id.* at 1264. In addition, while working lifetimes will vary, risk is significant for some who work as little as one year and, at any rate, individual and population risks are likely to remain the same so long as employees who leave one job are replaced by others, and those who change jobs remain within a covered sector. Nevertheless, the Agency solicits information regarding the likelihood of exposure to active TB in the workplace and duration of employment in various occupational groups. Lifetime risk estimates of TB infection by state are described in section 4.

Lifetime risk estimates of developing active TB are calculated from lifetime risk estimates of TB infection assuming that, once infected, there is a 10% likelihood of progressing to active TB. These estimates are discussed in section 4. Further, the number of deaths caused by TB is calculated from the lifetime estimates of active TB using OSHA's estimate of TB case fatality rate, also discussed in section 4.

1. Definitions

For the purpose of estimating incidence rates, *TB infection* rate is defined as the annual probability of an individual converting from negative to positive in the tuberculin skin test. *Annual occupational* risk is defined as the annual excess risk of becoming infected with TB due to occupational exposure, and is estimated as a function of the background risk. *Lifetime occupational risk* is defined as the excess probability of becoming infected with TB due to exposure in the workplace, at least once, in the course of a 45-year working lifetime and is estimated as $\{1-(1-p)^{45}\}$ where p is the annual occupational risk of TB infection.

2. Data Sources for Estimating Occupational Risk

The quantitative data needed to develop an overall national estimate of risk for TB infection due to occupational exposure are not available. The CDC does not publish occupational data associated with TB infection incidence 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 that capture occupational information in a systematic way.

However, there are a number of sources that permit the risk in occupational settings to be reasonably estimated and, with the aid of mathematical models, to develop estimates of excess relative occupational risk (ERR_o), which can then be multiplied by the state-specific background rates to yield estimates of excess occupational risk. OSHA has identified three data sources that are suitable for assessing the excess risk of TB infection in health care workers with occupational exposure. These include: (1) A 1994 survey of tuberculin skin testing in all health care facilities in Washington State; (2) A state-wide survey of hospitals in North Carolina, conducted in 1984–1985, which addressed TB skin testing practices, TB infection prevalence, and TB infection incidence among hospital employees in that state; and (3) the employee tuberculin skin test conversion database from Jackson Memorial Hospital in Miami, Florida. In addition to these hospital employee data, the Agency has obtained data on selected other work groups from the state of Washington. These groups include workers employed in long-term health care, home health care, and home care.

On the issue of data availability for this risk assessment, Dr. Graham agrees with OSHA that there are no comprehensive data available with respect to occupational risk of TB infection in health care and other institutions in the U.S. Instead of relying on two state specific studies, Dr. Graham recommends, though with serious reservations, the use of a review study by Menzies et al. (Ex. 7–130). Dr. Graham admits that the ''validity of the estimates in these reports [reviewed in the Menzies et al. study] must be open to serious question * * *'' for the following reasons, which were pointed out by Dr. Graham: several of the studies reviewed are very old and not relevant to TB risk in the 1990s; four studies use tine tests and self-reports of skin test results, which are not useful for estimation of risk of TB infection; the studies were not consistent in the inclusion of high and low risk workers; two-step testing was not done; and the participation rates were extremely low or unreported in many of the studies included in this review.

OSHA has chosen not to rely on the Menzies et al. review study, because, in addition to Dr. Graham's reservations (which the Agency shares), OSHA is also concerned about the inclusion in the Menzies et al. review article of studies conducted outside the U.S. Factors known to affect the epidemiology of TB, such as environmental conditions, socio-economic status, and work practices, are expected to differ greatly from one country to another, and are not controlled for in the statistical analyses of these studies. For all of these reasons, the Agency has chosen to rely solely on U.S. studies for its quantitative risk estimations.

Estimates of excess risk due to occupational exposure are expressed as the percent increase above background based on relative risk estimates derived from occupational studies. Internal control groups provided estimates of background risk for the Washington state and Jackson Memorial data sets. In the absence of a suitable internal control group, the estimated annual state-wide TB infection rate, as calculated in Section 3, was used as the background rate in the North Carolina study.

(a) *Washington State Data:* Initially, OSHA relied on a three-year prospective study, conducted between 1982 and 1984 in the state of Washington, to derive an estimate of excess risk for TB infection as a result of occupational exposure (Ex. 7–42). OSHA received several objections to the use of this study. The study used hospitals with no known TB cases as ''controls'' based on the assumption that in those hospitals the risk of TB infection to employees may be the same as for the general population. Dr. Qaqish noted that this assumption is highly questionable and that the use of such controls is not appropriate. Dr. Graham and Dr. Qaqish pointed out that the published results did not include conversions identified through contact investigations, which

means that the conversion rate reported in that study was likely to be an underestimate of the true risk. In addition, the commenters noted that the study was designed to estimate the effectiveness of the TB screening program and may have produced skin testing results biased toward the null; the study is relatively old; and, the study was conducted prior to the AIDS epidemic and therefore the results may not be relevant to the occupational risk at present because the relationship between HIV and TB is not reflected in this study.

In an effort to respond to reviewers' comments, the Agency chose to update the analysis by relying on a data set of tuberculin skin testing results from a survey of the state's tuberculin skin testing program in 1994. This survey is conducted by the TB Control Office in the Washington State Health Department and it covers all hospitals in the state, as well as long-term care, home health care, and home care facilities. OSHA was given access to the database for the 1994 survey as well as data on conversions identified through contact investigations for the same year (Ex. 7–263). Table V–2 summarizes the results of the 1994 survey. Of the 335 health care establishments in the state of Washington, 273 responded to the survey, for an overall response rate of 81.5%. Of those, 76 were hospitals, 142 were long-term care, 47 were home health care, and 8 were home care facilities. Hospitals had the highest survey response rate (85%) and home health care had the lowest (77%). Every employee at risk for TB infection (i.e., who was known to be tuberculin skin test negative at the start of the study period) in the participating hospitals and long-term care facilities was given a tuberculin skin test, including administrators, housekeepers, business office staff, and all part-time employees. Testing in home health care facilities was generally confined to those nursing staff who had direct client contact. Employees in home care are those who provide services to patients in home health care and include food handlers, cleaning aides, personal care-givers, and some social workers.

TABLE V–2—WASHINGTON STATE 1994 SURVEY RESULTS

Type of facility	Number of [a] establishments	Number of skin tests	Number of conversions	Annual rate of TB conversion
Hospital	76 (85%)	39,290	50	1.27/1,000
Long-term Care	142 (81%)	11,332	111	9.80/1,000
Home Health Care	47 (77%)	2,172	11	5.06/1,000
Home Care	8 (80%)	537	1	1.86/1,000
Total	273 (81.5%)	53,331	173	3.24/1,000

[a] Numbers in parentheses are study response rates for each group.

The overall rate of skin test conversion for workers in the health care system in Washington State in 1994 was 3.24 per 1,000 employees tested. This is greater than a 4-fold increase from the estimated state-wide background rate of 0.69 per 1,000 at risk, as calculated in section 3. The annual rate of TB conversion ranged from 1.27 per 1,000 tested for hospital employees to 9.80 per 1,000 tested for long-term care employees.

The annual rate of 9.8 per 1,000 for long-term care employees probably reflects the high potential for exposure to undiagnosed active TB in those facilities. As a rule, long-term facilities in Washington State do not have AFB isolation rooms. Therefore, residents with no obvious TB symptoms but who might be infectious spend most of their time in open spaces exposing other residents and workers to infectious droplet nuclei. However, once a resident has been identified as a suspect TB patient, that person is transferred to a hospital until medically determined to be non-infectious.

Also, since employees who were 35 years of age or younger were not given a two-step test at hiring, and a high percentage of employees are foreign born and therefore most likely to have been vaccinated during childhood with the BCG vaccine, some of the conversions observed might be late boosting because of BCG. However, an almost two-fold increase in risk for long-term care workers even as compared to the significant excess risk among home health care workers clearly indicates that the risk of TB infection for workers in long-term care is high and not likely to be fully explained by late boosting. Beginning in 1995, two-step testing has been done on all new hires in Washington State. Thus, tuberculin skin testing data for 1995 are not expected to be influenced by possible late boosting; OSHA will place the 1995 data in the rulemaking record as they become available.

Hospital workers had the lowest overall rate of conversion (overall rate of 1.27 per 1,000). This, in part, can be attributed to the existence of extensive TB control measures in that environment in Washington State. Compliance with the CDC Guidelines and OSHA's TB Compliance Directive is quite high in Washington State because: (a) There is a strong emphasis on early identification of suspect TB patients; (b) there is a strong emphasis on employee training and regular tuberculin skin testing (although on a less-frequent basis than recommended in the Guidelines: All employees are tested at hire and annually thereafter); (c) the use of respirators is expected when entering an isolation room; and (d) all isolation rooms are under negative pressure, have UV lights, and exhaust to the outside. In addition, conversion data in hospitals are more likely to represent true TB infections than in the other health care settings, because hospitals are more likely to re-test converters in an effort to eliminate false-positive cases.

A more thorough analysis of the hospital data is presented in table V–3. Because the Washington State survey was not designed to compare exposed persons with matched controls who have had no exposure, several alternative definitions of an internal control (unexposed) group were used in analyzing this data set. Three different analyses, shown in table V–3, produced estimates of annual occupational infection rates ranging from 0.4 to 0.6 per 1,000 above control (i.e., ranging from a 47% to an 84% increase above control). In order to minimize the likelihood of contaminating the control group with persons having significant occupational exposure, OSHA defined the control group as workers in hospitals located in zero-TB counties and with no known TB patients. This analysis is summarized in table V–3 as Definition 1. If potential for occupational exposure is defined as

either working in a hospital in a county that has active TB or in a hospital that has had TB patients, then the annual risk due to occupational exposure is 47% above background. The excess annual risk due to occupational exposure appears to be approximately 60% above background, if workers in hospitals with a transfer-out policy for TB patients are considered to be the control group, shown as Definition 2 in table V–3. A 60% increase above background is not statistically significantly different from a 47% increase and therefore these two ''control'' groups can be viewed as producing ''statistically'' equivalent results. However, the Agency believes that Definition 1 is more appropriate, though the risk estimates are higher if the control group is defined based on Definition 2, because there is a higher likelihood of potential for exposure to a patient with undiagnosed TB under Definition 2 conditions. Comparisons of all hospital TST data to the state-wide estimate of TB infection rate resulted in an estimate of the annual excess occupational risk of approximately 84% above background, shown in table V–3 as Definition 3. Estimates of the annual and lifetime occupational risk of TB infection for the average health care worker in hospitals by state, extrapolated from this study and using Definition 1 as the control group, are presented and summarized in section 4.

TABLE V–3—WASHINGTON STATE DATA HOSPITAL PPD SKIN TESTING RESULTS

Definition of exposed and control groups	Sample size	Number of skin tests given	Number of conversions observed	Average conversion rate 1 [a]	Overall conversion rate 2 [b]	Relative risk	
						Rate 1	Rate 2
Definition 1							
Control: Hospitals in zero-TB counties and with no-known TB patients	16	1,142	1	0.477	0.8756	.....	.....
Exposed: Hospitals in counties reporting TB or having TB patients	60	38,148	49	1.523	1.28447	3.19	1.47
Definition 2							
Control: Hospitals that transfer out TB patients	35	3,645	3	0.498	0.823	.....	.....
Exposed: Hospitals with isolation rooms	41	35,645	47	1.989	1.3185	3.99	1.602
Definition 3							
Control: State-wide estimates of annual risk of infection	.....	.....	.....	[c]0.69	[c]0.69	.....	.....
Exposed: All PPD testing data	76	39,290	50	1.302	1.27	1.89	1.84

[a]Rate 1 is estimated as the arithmetic average of hospital specific conversion rates.
[b]Rate 2 is estimated as the ratio of the sum of all conversions reported divided by the total number of skin tests given within each group.
[c]Source: Table V–3(b), state-wide rate of infection.

Annual rates of excess risk due to occupational exposure were estimated for long-term care, home health care, and home care and are presented in Section 4. The same control group used in the hospital data analysis, Definition 1 (i.e., 0.876/1,000 workers at risk) was used to estimate the background risk among workers in long-term care, health care, and home care facilities and settings. Using 0.876 as the background infection rate for workers in these settings (a) provided a level of consistency among the Washington data analyses, and (b) resulted in a lower estimate of occupational risk for the non-hospital health care workplaces than would have resulted had the state-wide background risk estimate (i.e., 0.67/1,000 see Section 3) been used. When industry-specific risk data are used, there is approximately a 10-fold increase in annual risk for workers in long-term care, a 5-fold increase in annual risk for workers in home health care, and a 1-fold increase in annual risk for workers in home care (see Section 4).

Estimates of the range of annual and lifetime occupational risk for the average health care worker in long-term care, home health care, and home care by state, extrapolated from the Washington State study, are presented in Section 4.

(b) *North Carolina Study:* A state-wide survey of all hospitals in North Carolina (NC) was conducted in 1984–1985 (Ex. 7–7). The survey's questionnaire was designed to address three main areas of concern affecting hospital employees: (1) Tuberculin skin testing practices; (2) TB infection prevalence; and (3) TB infection incidence. The incidence of new infections among hospital personnel was assessed over a five-year period by reviewing tuberculin skin test conversion data during calendar years 1980 through 1984 and was calculated as the number of TB skin test conversions divided by the number of skin tests administered. (Since most employees were only given annual testing, the number of tests administered is a very close estimate of the total number of people tested within a year and thus can be used as the denominator in estimating infection incidence.) Only 56 out of 167 hospitals reported information on TB conversion rates (34% response rate). The authors estimated a state-wide TB infection rate of 11.9 per 1,000 per year for hospital employees in 1984 and a five-year mean annual infection rate of 11.4 per 1,000, with a range of 0-89 per 1000 employees at risk for TB infection. An analysis of the data by region (i.e., eastern, central, western) showed that the eastern region had consistently higher rates (with an average infection rate of 18.0 per 1,000) followed by the central region (7.0 per 1,000) and the western region (6.1 per 1000). Results of this study are shown in table V–4.

TABLE V–4—SKIN TEST CONVERSION RATES [a] NORTH CAROLINA HOSPITAL PERSONNEL [b]

Region	Year					
	1980	1981	1992	1993	1984	5-year mean
Eastern	19.3 (7)	30.8 (10)	17.7 (11)	11.2 (12)	15.7 (18)	18.0 (19)
Central	3.0 (6)	3.7 (8)	7.2 (13)	6.6 (23)	10.0 (25)	7.0 (29)
Western	1.9 (2)	13.5 (4)	5.3 (4)	4.1 (4)	7.2 (8)	6.1 (8)

[a] Conversion rates are expressed as number of conversions per 1,000 workers tested.
[b] In parentheses is the number of hospitals included in the study.

Use of this study's overall results for risk estimates was criticized by the peer reviewers because of design flaws in the study (e.g., high non-response rate, inconsistent skin testing practices, and limited two-step testing) and, most importantly, the presence of atypical mycobacteria (contributing to false positive results) in the eastern part of the state. Based on further input from Dr. Comstock, the Agency chose to rely on the study results from the western region only, because they are considered to be more representative of the ''true'' risk of infection and are expected to be less confounded by cross-reactions to atypical mycobacteria. Further, the Agency chose to rely on the conversion rate estimated for 1984 because it was the most recent data reported in the study. Therefore, the western region conversion rate of 7.2 per 1,000, estimated based on responses to the survey from eight hospitals in 1984, was used as an overall worker conversion rate. Further, the 1984 rate was adjusted by the percent decrease of active TB between 1984 and 1994 in North Carolina so that the final worker conversion rate for 1994 based on the western region rates reported in this study was estimated to be 5.98 (7.2 * 532/641 = 5.98) per 1,000 employees at risk for TB infection.

The North Carolina study did not have an internal control group to use as the basis for estimating excess risk due to occupational exposure because the conversion rates presented in this study were based on TST results for the entire hospital employee population. In the absence of an internal control group, the Agency used the estimated state-wide background rate of 1.20 per 1,000 as the background rate of infection for the western region in North Carolina (see Section 3) to estimate excess risk due to occupational exposure.[1] Based on this study, annual occupational risk is approximately four times greater than background [(5.98–1.2)/1.2 = 3.98]. Estimates of the annual and lifetime occupational risk of TB infection based on this study by state are presented in Section 4.

(c) *Jackson Memorial Hospital Study:* Jackson Memorial Hospital (JMH) is a 1500-bed general facility located in Miami, Florida, employing more than 8,000 employees. It is considered one of the busiest hospitals in the U.S. It is the primary public hospital for Dade County and the main teaching hospital for the University of Miami School of Medicine. JMH treats most of the TB and HIV cases in Dade County and, consequently, there is a higher likelihood of occupational exposure to TB in this facility than in the average hospital in the U.S. From March 1988 to September 1990, an outbreak of multidrug-resistant TB (MDR–TB) occurred among patients and an increased number of TST conversions was observed among health care workers on the HIV ward. This prompted a re-evaluation of the hospital's infection control practices and the installation of engineering controls to minimize exposure to TB. As part of the evaluation of the outbreak, NIOSH did a Health Hazard Evaluation and issued a report (Ex. 7–108). In addition, NIOSH conducted a retrospective cohort study of JMH to determine whether the risk of TB infection was significantly greater for health care workers who work on wards having patients with infectious TB than those who work on wards without TB patients.

For the data analysis of this study, ''potential for occupational exposure'' was defined based on whether an employee worked on a ward that had records of 15 or more positive cultures for pulmonary or laryngeal TB during 1988–1989. In other words, positive culture was taken as a surrogate for exposure to infectious TB. The authors restricted the ''exposed'' group to employees on wards with exposures to pulmonary or laryngeal TB because they intended to restrict the study to hospital workers with exposure to patients with the highest potential for being infectious. There were 37 wards at JMH that had submitted at least one positive culture during 1988–1989. Seven wards met the criteria of 15 or more and were therefore included in the ''exposed'' group. These were the medical intensive care unit, five medical wards, and the emergency room. The ''control'' group was defined as hospital workers assigned to wards with no TB patients (i.e., wards with no records of positive cultures during 1988–89). The ''control'' wards were post-partum, labor and delivery, newborn intensive care unit, newborn intermediate care unit, and well newborn unit. The results of this analysis are presented in Table V–5.

TABLE V–5—SKIN TEST CONVERSION RATES FOR HOSPITAL PERSONNEL AT JACKSON MEMORIAL HOSPITAL [a, b]

Year	Exposed group	Control group	Relative risk	95% confidence interval
1989	62.2 (13/209)	6.2 (2/324)	10.1	2.3—44.2

[1] Using the state-wide estimate of population risk as the background estimate of risk for this study most likely results in an underestimate of the true excess risk due to occupational exposure, because the true background estimate of risk for the western region in North Carolina is expected to be less than the state-wide estimate, which is influenced by the large number of infections found in the eastern region of that state.

TABLE V–5—SKIN TEST CONVERSION RATES FOR HOSPITAL PERSONNEL AT JACKSON MEMORIAL HOSPITAL [a, b]—Continued

Year	Exposed group	Control group	Relative risk	95% confidence interval
1990	75.5 (16/212)	6.5 (2/309)	11.7	2.7—50.2
1991	31.7 (6/189)	3.5 (1/282)	9.0	1.1—73.8

[a] Rates are expressed as number of conversions per 1,000 workers tested.
[b] Source: Ex. 7–108

Table V–5 shows a substantially elevated risk for those workers with potential exposure to patients with infectious TB. The relative risk ranges from 9 to 11.7 between 1989 and 1991 and is statistically significant for all of those years. This suggests that the excess risk due to occupational exposure is approximately 8-fold above background; this is an overall risk estimate that reflects the occupational risk of TB infection for JMH employees with patient contact, because this analysis included everyone tested in the ''exposed'' and ''control'' group, regardless of his or her specific job duties or length of patient contact.

An analysis of various occupational groups within this cohort showed that nurses and ward clerks in the ''exposed'' groups had the highest conversion rates: 182 and 156 conversions per 1,000 workers tested, respectively. Other studies have shown that health care workers who provide direct patient care are at greater risk for infection than workers who do not provide direct patient care. The high risk seen in ward clerks was unexpected since these workers are not involved in direct patient care. However, in the emergency room, the risk for TST conversion for the ward clerks was almost three times higher than for the nurses, 222 and 83 per 1,000, respectively. Ward clerks in the emergency room are responsible for clerical processing of patients after triage, handling specimens for the laboratory, and gathering clothing and valuables from admitted patients. During these interactions, there may have been less strict adherence to infection control measures, and this could explain the high conversion rate.

OSHA used the results from the 1991 analysis of the data in the JMH study to estimate occupational risk of TB infection in hospital workers with a relatively high likelihood of occupational exposure, for the following reasons: (a) 1991 represents the most recent year for which conversion data are available prior to the time when TB infection control measures were fully implemented at JMH; and (b) The higher conversion rates reported for 1990 and 1989 (75.5 and 62.2 per 1,000 respectively) may be atypical, i.e., they may to some extent reflect the effect of the outbreak and not the long-term occupational risk.

Based on the results of this study, OSHA estimates that the annual excess risk of TB infection due to occupational exposure is 7.95 times greater than background. Estimates of annual and lifetime occupational risk of TB infection for the average health care worker in hospitals by state, extrapolated from this study, are presented and summarized in section 4.

3. Estimation of Background Risk of TB Infection

OSHA's methodology for estimating population (background) TB infection rates relies on the assumption that TB infection occurring in an area can be expressed as a numerical function of active TB cases reported in the same area. If the likelihood of observing any infection in a population is minimal, then the likelihood of observing active disease diminishes. Conversely, the presence of active TB implies the presence of infection, since active disease can only progress from infection. Therefore, there is a functional relationship linking TB infections to active disease being observed in a particular area during a specified time period.

Peer reviewer comments on this assumption varied. Neil Graham states in his comment ''Although factors such as migration and distribution of the population may influence this relationship it seems probable that this assumption is largely correct and justifiable.'' (Ex. 7–271). On the other hand, Dr. Simone expresses concern over this assumption and states ''It is not necessarily true that a change in cases now reflects the risk of infection now.'' Dr. Qaqish demonstrates in his comment that the net effect of assuming a proportional relationship between the number of active cases and the number of new infections is to introduce a possible bias into the estimate of background risk of TB infection, although such a bias could work in either direction, i.e., toward increasing or decreasing the estimate of risk. Dr. Qaqish further states that in the absence of more ''relevant data,'' it is not possible to determine the actual net effect in magnitude and direction of the bias and ''without obtaining additional data, it would be impossible for the Agency to improve on the accuracy of the risk estimates * * *'' OSHA has considered all of the reviewer comments and is aware of the inherent uncertainty and the potential for bias associated with the use of this assumption; however, in the absence of the additional ''relevant'' data to which Dr. Qaqish refers, the Agency believes this approach to be justifiable.

In defining the model used to estimate the annual infection rates occurring in a geographical area based on data on active disease cases reported for the same area, infections progressing to active disease are assigned to one of three distinct groups: those occurring this year, last year, and in previous years.

BILLING CODE 4510–26–P

```
   This        Last
  year's      year's          Previous
infections  infections   years' infections
    \           |          / / / /..../
     \          |         / / / /..../
      \         |        / / / /..../
       \        |       / / / /..../
        \       |      / / / /..../

This year's active TB cases
```

BILLING CODE 4510–26–C

TB cases reported to CDC each year are a combination of new and old infections that have, for various reasons, progressed to active disease. Until recently, it was believed that most of the active cases were the product of old infections. However, with the use of DNA fingerprinting techniques, researchers have reported that a larger percentage of active cases may be attributed to new or recent infections. Small *et al.* reported, in an article on tracing TB through DNA fingerprinting, that as many as 30% of the active cases reviewed in the study may be the result of recent infections (Ex. 7–196).

In this risk assessment, the Agency assumes the lifetime risk that an infection will progress to active TB to be approximately 10%. This estimate is supported by CDC and in her comment, Dr. Simone states that: ''The assumption * * * is generally agreed upon.'' Dr. Comstock and Dr. Qaqish both questioned the validity and accuracy of CDC's estimate. Their comments suggest that the true lifetime rate of progression from infection to active disease for adults may be less than 10 percent. However, as Dr. Graham points out, the 10% assumption is a widely accepted ''rule of thumb'' and is also in relative agreement with data from the unvaccinated control group of the British Medical Research Council (MRC) vaccination trial in adolescents (Ex. 7–266).

In the MRC study, 1,338 adolescents' skin tests converted following TB exposure where the precise date of conversion was known. Of these, 108 (8.1%) individuals developed active TB during follow-up. Of these, 54% developed active TB within one year and 78% within 2 years. This results in a risk of approximately 4% at one year, 6% at two years, and an overall risk of 8%. Given that the risk of TB reactivation increases with age, the lifetime risk is expected to be higher than the 8% attained in this study and, as Dr. Graham points out, a 10% overall lifetime risk seems reasonable.

Based on Dr. Graham's recommendation to rely on the progression rates from the MRC study, OSHA changed the assumption on the progression parameters from 2.5% (first year), 2.5% (second year), and 5% (remaining lifetime) to 4%, 2% and 4%, respectively. Therefore the total 10% progression from infection to active disease is partitioned into 3 groups: progression during the first year after infection (40% of all infections that eventually progress, for a net probability of 4%), progression during the second year (20% of all infections that eventually progress, for a net probability of 2%), and progression during all subsequent years (the remaining 40% of progressing infections). This last probability (4%) is assumed to be uniformly distributed across the remaining lifespan.

TB rates vary considerably by geographic area, socio-economic status, and other factors. In an attempt to account for some of those factors, to the extent possible, background TB infection rates have been estimated separately for each state. The derivation of background infection rates involves several steps for which the process and formulae are presented below.

Step 1: Background rate of TB infection for state i in year j is defined as:

$$B_{i(j)}=I_{i(j)}/X_{i(j)} \qquad (1)$$

where:

$B_{i(j)}$ is the background TB infection rate for state i in year j

$I_{i(j)}$ is an estimate of the number of new infections that occurred in state i in year j

$X_{i(j)}$ is the population at risk for TB infection in state i in year j.

Step 2: Estimation of $I_{i(j)}$, the number of new TB infections:

Let:

$A_{i(j)}$ be the total number of adult TB cases reported to CDC by state i in year j.

$A_{(j)}$ be the total number of adult TB cases reported to CDC by all states in year j.

$P_{i(j)}$ be the estimated prevalence of adult TB infection in state i during year j.

R_i be the ratio of the number of adult TB cases reported in 1993 to the number of adult cases reported in 1994 in state i.

The number of TB cases reported in 1994 can be expressed as a function of TB infections expected to have progressed to active disease, by the following formula:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*I_{i(1992)}*\text{prob(alive in 1994)}$$
$$+(.04/73)*I_{i(1991)}*\text{prob(alive in 1994)}$$
$$+....$$
$$+....$$
$$+(.04/73)*I_{i(1919)}*\text{prob(alive in 1994)}$$

This can be expressed as:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*\Sigma\,[I_{i(j)}*\text{prob(alive in 1994)}],$$

where j ranges from 1919 to 1992. The quantity inside the summation symbol is the sum of all people who were infected with TB between 1919 and 1992 and are still alive in 1994. This summation can be approximated by the prevalence of TB infection in 1992, $P_{i(1992)}$. Therefore, the number of active TB cases reported in 1994 can be expressed as:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*P_{i(1992)} \qquad (2)$$

Further, if we assume that the number of new infections is directly proportional to the number of active cases, then $I_{i(1993)}$ can be expressed as follows:

$$I_{i(1993)}=I_{i(1994)}*(A_{i(1993)}/A_{i(1994)}) \qquad (3)$$

and (2) can be expressed as:

$$A_{i(1994)}=[(.02*(A_{i(1993)}/A_{i(1994)})+.04]*I_{i(1994)}+(.04/73)*P_{i(1992)}$$
$$A_{i(1994)}=[(.02*R_i+.04]*I_{i(1994)}+(.04/73)*P_{i(1992)} \qquad (4)$$

then solving for $I_{i(1994)}$ becomes: [2]

[2] Using the prevalence of TB infection in 1992 (i.e., $P_{i(1992)}$) to approximate the quantity inside the summation sign (i.e., everyone infected between 1919 and 1992 and alive in 1994) slightly overestimates the quantity inside the summation (i.e., $P_{i(1992)}$ is slightly larger than the quantity it approximates.) It includes a small number of people

$I_{i(1994)}=[A_{i(1994)}-.04/73*P_{i(1992)}]/(.02*R_i+.04)$ (5)

Step 3: Estimation of $X_{i(1994)}$:

$X_{i(1994)}$, the population at risk for TB infection in state i in 1994, is estimated as follows:

$X_{i(1994)}=N_i-P_{i(1993)}$ (6)

Where:

N_i is the adult population for state i as reported by U.S. Census in 1994.

$P_{i(1993)}$ is the estimated number of infected adults in state i in 1993 (i.e., prevalence of TB infection in state i among adults).

To estimate the number of adults currently at risk for TB infection in each state, the number of already infected adults (i.e., prevalence of TB infection P_i in 1993) is subtracted from the adult population in 1994.

Step 4: Estimation of population currently infected as of 1993 by state, $P_i(1993)$:

The prevalence of TB infection in each state is estimated as a function of TB infection prevalence in the U.S. in 1993 and the percent TB case rate for each state.

$P_{i(1993)}=P_{(1993)}*(A_{i(1993)}/A_{(1993)})$ (7)

Where:

$P_{(1993)}$ is the prevalence of TB infections in the U.S. in 1993 (Ex. 7–66) and

$A_{(1993)}$ is the total number of adult TB cases reported in 1993.

Estimates of TB infection prevalence in the U.S. were developed for OSHA by Dr. Christopher Murray of the Harvard Center for Population and Development Studies and are presented in Table V–6 (Ex. 7–267). The mathematical model used by Dr. Murray to estimate TB infection prevalence has been designed to capture the transmission dynamics of TB by modeling transfers between a series of age-stratified compartments using a system of differential equations. The model adjusts for various epidemiological factors known to influence the course of active TB, such as onset of infection (i.e., old vs. new infections) and the impact of immigration rates and the HIV epidemic. However, it does not differentiate among gender or race categories. The model has been successfully validated using actual epidemiological data on active TB from 1965 to 1994. The estimates of TB prevalence rates presented here are specific for adults (i.e., older than 18 years of age), which make them more appropriate for estimating risk of transmission in an occupational setting.

TABLE V–6.—NATIONAL PREVALENCE OF TB INFECTION IN ADULTS (18+) [a] [b]

Year	Expected	Minimum	Maximum
1992	6.87% (12,978,461)	6.53% (12,336,150)	7.22% (13,639,663)
1993	6.64% (12,667,062)	6.31% (12,037,524)	6.97% (13,296,599)
1994	6.47% (12,449,445)	6.14% (11,814,465)	6.79% (13,065,182)

[a] Numbers in parentheses are population prevalence figures.
[b] Estimated for OSHA by Christopher Murray MD, PhD, Harvard University, Center for Population and Development Studies (Ex. 7–267).

To estimate the number of previously infected adults in each state (P_i), the estimated national TB prevalence figure was multiplied by the active cases for each state and divided by the total number of active cases reported [see equation (7)] (i.e., the national prevalence estimate was apportioned among the states based on each state's percent contribution to active TB reported for 1993). To estimate the number of adults at risk of TB infection, (X_i), the number of already infected adults was subtracted from the adult population estimate for each state (see equation (6)). The number of new infections expected to have occurred in 1994 was estimated using equation (5).

The background rate of TB infection for 1994 was then estimated by dividing the number of new infections (I_i) by the number of susceptible adults in each state (X_i) (see equation (1)).

Results on estimated TB background annual infection rates for each state are presented in Table V–7(a)—Table V–7(c). In Table V–7(a) TB infection rates are based on an average value of TB infection prevalence, as estimated by Dr. Murray, in the U.S. (i.e., 12,667,062). In Table V–7(b), infection rates are based on the minimum value of TB infection prevalence in the U.S. (i.e., 12,037,524). In Table V–7(c), infection rates are based on the maximum value of TB infection prevalence in the U.S. (i.e., 13,296,599). An overall range of background annual TB infection rates was constructed by combining all three sets of infection rates and was estimated to be between 0.194 and 3.542 per 1,000 individuals at risk of TB infection, with a weighted average of 1.46 per 1,000 using state population size as weights.

TABLE V–7(a).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES [a]

[Referent Year 1994]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_{i(1993)}$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Alabama (01)	413	3,139	250,083	2,888,917	4,779	1.65
Alaska (02)	78	414	27,787	386,213	1,182	3.06
Arizona (04)	233	2,936	118,231	2,817,769	2,858	1.01
Arkansas (05)	235	1,813	107,334	1,705,666	2,906	1.70
California (06)	4,291	22,754	2,437,044	20,280,956	47,852	2.36

who were infected with TB and were alive as of 1992 and who were therefore included in the prevalence figure, but who died before 1994, and, technically, are not included in the summation. This implies that, in equation (5), a slightly larger number is being subtracted from $A_{i(1994)}$ than should be, resulting in an underestimate of the number of new infections in 1994 and an underestimate of the occupational risk.

TABLE V–7(a).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES [a]—Continued

[Referent Year 1994]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_{i(1993)}$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Colorado (08)	90	2,686	52,850	2,633,150	1,045	0.40
Connecticut (09)	144	2,487	81,182	2,405,818	1,665	0.69
Delaware (10)	51	531	26,152	504,848	671	1.33
D.C. (11)	116	451	80,092	370,908	1,162	3.13
Florida (12)	1,675	10,691	846,687	9,844,314	20,545	2.09
Georgia (13)	676	5,162	396,646	4,765,354	7,082	1.49
Hawaii (15)	234	875	132,942	742,058	25,890	3.49
Illinois (17)	1,021	8,669	622,211	8,046,789	10,994	1.37
Indiana (18)	201	4,279	129,673	4,149,327	2,083	0.50
Iowa (19)	62	2,180	31,056	2,068,943	859	0.42
Kansas (20)	77	1,864	37,049	1,826,951	1,065	0.58
Kentucky (21)	316	2,857	203,227	2,653,773	3,273	1.23
Louisiana (22)	412	3,080	185,792	2,894,208	5,582	1.93
Maine (23)	31	934	14,712	919,289	419	0.46
Maryland (24)	344	3,743	211,399	3,531,601	3,582	1.01
Massachusetts (25)	299	4,617	183,067	4,433,933	2,889	0.65
Michigan (26)	438	6,971	246,269	6,724,731	5,036	0.75
Minnesota (27)	127	3,326	68,105	3,257,895	1,413	0.43
Mississippi (28)	262	1,913	141,659	1,771,341	3,120	1.76
Missouri (29)	241	3,899	128,583	3,770,417	2,922	0.78
Montana (30)	22	618	11,987	606,013	290	0.48
Nebraska (31)	22	1,181	12,531	1,168,469	233	0.20
Nevada (32)	111	1,181	50,670	1,130,330	1,514	1.34
New Hampshire (33)	17	845	13,076	831,924	182	0.22
New Jersey (34)	764	5,973	456,579	5,516,421	8,150	1.48
New Mexico (35)	78	1,156	35,415	1,120,585	944	0.84
New York (36)	3,414	13,658	2,044,797	11,613,203	34,728	2.99
North Carolina (37)	532	5,314	298,574	5,015,426	6,000	1.20
North Dakota (38)	10	466	3,813	426,186	132	0.29
Ohio (39)	318	8,248	161,274	8,086,726	3,763	0.47
Oklahoma (40)	231	2,378	101,886	2,276,114	3,064	1.35
Oregon (41)	146	2,303	78,457	2,224,543	1,793	0.81
Pennsylvania (42)	583	9,154	379,211	8,774,789	5,886	0.67
Rhode Island (44)	47	757	31,601	725,399	495	0.68
South Carolina (45)	362	2,712	205,406	2,506,594	4,273	1.70
South Dakota (46)	26	513	8,173	504,827	342	0.68
Tennessee (47)	494	3,878	283,863	3,594,137	5,759	1.60
Texas (48)	2,276	13,077	1,199,200	11,877,800	27,306	2.30
Utah (49)	47	1,236	23,973	1,212,027	427	0.35
Vermont (50)	10	434	2,724	431,276	160	0.37
Virginia (51)	330	4,949	226,110	4,722,890	3,220	0.68
Washington (53)	241	3,935	142,729	3,792,251	2,554	0.67
West Virginia (54)	80	1,393	40,318	1,352,682	919	0.68
Wisconsin (55)	104	3,735	50,126	3,684,874	1,307	0.35
Wyoming (56)	12	339	3,814	335,186	188	0.56

[a] Expressed in thousands.
[b] Based on 6.64% rate of TB infection prevalence in the U.S. (expected)

TABLE V–7(b).—Estimates of Annual Background TB Infection Rates

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_i(1993)$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Alabama (01)	413	3,139	237,654	2,901,346	4,871	1.68
Alaska (02)	78	414	26,406	387,594	1,196	3.09
Arizona (04)	233	2,936	112,355	2,823,645	2,913	1.03
Arkansas (05)	235	1,813	102,000	1,711,000	2,967	1.73
California (06)	4,291	22,754	2,350,136	20,403,864	48,956	2.40
Colorado (08)	90	2,686	50,223	2,635,777	1,066	0.40
Connecticut (09)	144	2,487	77,147	2,409,853	1,700	0.71
Delaware (10)	51	531	24,853	506,147	681	1.34
D.C. (11)	116	451	76,111	374,889	1,192	3.18

TABLE V–7(b).—Estimates of Annual Background TB Infection Rates—Continued

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] P_i(1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Florida (12)	1,675	10,691	804,607	9,886,393	20,944	2.12
Georgia (13)	676	5,162	376,933	4,785,067	7,275	1.52
Hawaii (15)	234	875	126,335	748,665	2,652	3.54
Illinois (17)	1,021	8,669	591,288	8,077,712	11,260	1.39
Indiana (18)	201	4,279	123,228	4,155,772	2,136	0.51
Iowa (19)	62	2,180	29,513	2,070,487	869	0.42
Kansas (20)	77	1,864	35,208	1,828,792	1,079	0.59
Kentucky (21)	316	2,857	193,126	2,663,874	3,357	1.26
Louisiana (22)	412	3,080	176,558	2,903,442	5,667	1.95
Maine (23)	31	934	13,980	920,020	425	0.46
Maryland (24)	344	3,743	200,893	3,542,107	3,677	1.04
Massachusetts (25)	299	4,617	173,969	4,443,031	2,983	0.67
Michigan (26) ,	438	6,971	234,030	6,736,970	5,144	0.76
Minnesota (27)	127	3,326	64,721	3,261,279	1,448	0.44
Mississippi (28)	262	1,913	134,619	1,778,381	3,183	1.79
Missouri (29)	241	3,899	122,193	3,776,807	2,978	0.79
Montana (30)	22	618	11,391	606,609	294	0.48
Nebraska (31)	22	1,181	11,909	1,169,091	240	0.21
Nevada (32)	111	1,181	48,152	1,132,848	1,536	1.36
New Hampshire (33)	17	845	12,426	832,574	185	0.22
New Jersey (34)	764	5,973	433,887	5,539,113	8,357	1.51
New Mexico (35)	78	1,156	33,655	1,112,345	965	0.86
New York (36)	3,414	13,658	1,943,173	11,714,827	35,735	3.05
North Carolina (37)	532	5,314	283,735	5,030,265	6,138	1.22
North Dakota (38)	10	466	3,624	462,376	134	0.29
Ohio (39)	318	8,248	153,259	8,094,741	3,845	0.48
Oklahoma (40)	231	2,378	96,822	2,281,178	3,116	1.37
Oregon (41)	146	2,303	74,558	2,228,442	1,825	0.82
Pennsylvania (42)	583	9,154	360,365	8,793,635	6,047	0.69
Rhode Island (44)	47	757	30,030	726,970	506	0.70
South Carolina (45)	362	2,712	195,197	2,516,803	4,356	1.73
South Dakota (46)	26	513	7,766	505,234	350	0.69
Tennessee (47)	494	3,878	269,756	3,608,244	5,875	1.63
Texas (48)	2,276	13,077	1,139,601	11,937,399	27,853	2.33
Utah (49)	47	1,236	22,782	1,213,218	446	0.37
Vermont (50)	10	434	2,589	431,411	162	0.37
Virginia (51)	330	4,949	214,873	4,734,127	3,311	0.70
Washington (53)	241	3,935	135,654	3,799,346	2,621	0.69
West Virginia (54)	80	1,393	38,315	1,354,685	941	0.69
Wisconsin (55)	104	3,735	47,634	3,687,366	1,332	0.36
Wyoming (56)	12	339	3,624	335,376	190	0.57

[a] Expressed in thousands.
[b] Based on a 6.31% rate of TB infection in the U.S.

TABLE V–7(c).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size N_i	Population currently infected [b] P_i (1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection, B_i
Alabama (01)	413	3,139	262,512	2,876,488	4,685	1.63
Alaska (02)	78	414	29,168	384,832	1,167	3.03
Arizona (04)	233	2,936	124,107	2,811,893	2,801	1.00
Arkansas (05)	235	1,813	112,669	1,700,332	2,843	1.67
California (06)	4,291	22,754	2,595,951	20,158,049	46,720	2.32
Colorado (08)	90	2,686	55,476	2,630,524	1,024	0.39
Connecticut (09)	144	2,487	85,216	2,401,784	1,629	0.68
Delaware (10)	51	531	27,452	503,508	661	1.31
D.C.	116	451	84,072	366,928	1,131	3.08
Florida (12)	1,675	10,691	888,766	9,802,234	20,137	2.05
Georgia (13)	676	5,162	416,359	4,745,641	6,884	1.45
Hawaii (15)	234	875	139,539	735,451	2,526	3.43
Illinois (17)	1,021	8,669	653,134	8,015,866	10,721	1.34

TABLE V–7(c).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES—Continued

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size N_i	Population currently infected [b] P_i (1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection, B_i
Indiana (18)	201	4,279	136,117	4,142,883	2,029	0.49
Iowa (19)	62	2,180	32,600	2,067,401	849	0.41
Kansas (20)	77	1,864	38,891	1,825,109	1,052	0.58
Kentucky (21)	316	2,857	213,327	2,643,673	3,187	1.21
Louisiana (22)	412	3,080	195,025	2,884,975	5,496	1.91
Maine (23)	31	934	15,442	918,558	413	0.45
Maryland (24)	344	3,743	221,905	3,521,095	3,484	0.99
Massachusetts (25)	299	4,617	192,166	4,424,834	2,793	0.63
Michigan (26)	438	6,971	258,508	6,712,492	4,925	0.73
Minnesota (27)	127	3,326	71,490	3,254,510	1′,377	0.42
Mississippi (28)	262	1,913	148,700	1,764,300	3,057	1.73
Missouri (29)	241	3,899	134,973	3,764,027	2,865	0.76
Montana (30)	22	618	12,582	605,418	286	0.48
Nebraska (31)	22	1,181	13,154	1,167,846	227	0.20
Nevada (32)	111	1,181	53,189	1,127,811	1,491	1.32
New Hampshire (33)	17	845	13,726	831,274	178	0.21
New Jersey (34)	764	5,973	479,270	5,493,730	7,938	1.44
New Mexico (35)	78	1,156	37,175	1,118,825	922	0.82
New York (36)	3,414	13,658	2,146,421	11,511,421	33,696	2.92
North Carolina (37)	532	5,314	313,413	5,000,587	5,859	1.17
North Dakota (38)	10	466	4,003	461,997	129	0.28
Ohio (39)	318	8,248	169,289	8,078,711	3,678	0.46
Oklahoma (40)	231	2,378	106,949	2,271,051	3,011	1.33
Oregon (41)	146	2,303	82,357	2,220,643	1,760	0.80
Pennsylvania (42)	583	9,154	398,057	8,755,943	5,722	0.66
Rhode Island (44)	47	757	33,171	723,829	483	0.67
South Carolina (45)	362	2,712	215,614	2,496,386	4,188	1.68
South Dakota (46)	26	513	8,579	504,421	334	0.67
Tennessee (47)	494	3,878	297,971	3,580,029	5,641	1.58
Texas (48)	2,276	13,077	1,258,799	11,818,201	26,746	2.26
Utah (49)	47	1,236	25,165	1,210,835	408	0.34
Vermont (50)	10	434	2,860	431,140	158	0.37
Virginia (51)	330	4,949	237,347	4,711,653	3,126	0.66
Washington (53)	241	3,935	149,843	3,785,157	2,485	0.66
West Virginia (54)	80	1,393	42,322	1,350,679	896	0.66
Wisconsin (55)	104	3,735	52,617	3,682,383	1,283	0.35
Wyoming (56)	12	339	4,003	334,997	185	0.55

[a] Expressed in thousands.
[b] Based on 6.97% rate of TB infection prevalence in the U.S. (maximum estimate).

Step 5 Model validation:

An alternative, but less sophisticated, way to estimate annual risk of infection, if prevalence is known in a specific age group, is to use the following formula:

Annual Rate of Infection = -ln(1-P)/d (8)

Where:

P is the percent prevalence of infection and

d is the average age of the population (Ex. 7–265).

In order to validate the model used by OSHA to estimate background infection rates, estimates of TB infection prevalence for 1994 were used to calculate predicted infection rates using equation (8). Based on Murray's model, TB infection prevalence is expected to range from 6.31% to 6.97% in 1994 among adults (18+). Using these figures and assuming the average age to be 45 years, formula (8) predicts that infection rates can range from 1.45 to 1.61 per 1,000. These results are in close agreement with OSHA's weighted average estimate of the national TB infection rate, which is 1.46 per 1,000.

4. Occupational Risk Estimations

OSHA used the three different data sources to obtain estimates of risk of TB infection for health care employees: the Washington State data, the North Carolina study, and the NIOSH Health Hazard Evaluation (HHE) from Jackson Memorial Hospital (Exs. 7–263, 7–7, 7–108). The Washington State data represent workplaces located in low TB prevalence areas, where TB infection control measures and engineering controls are required by state health regulations. The North Carolina data represent workplaces located in areas with moderate TB prevalence and inadequate TB infection control programs. Finally, the Jackson Memorial Hospital data are representative of county hospitals serving high-risk patients whose employees have a high frequency of exposure to infectious TB. These data sources provide information on the magnitude of the expected excess risk in three different environments, and are used to provide a range of possible values of excess risk.

Based on the Washington State data, the annual risk is expected to be 1.5 times the background rate for hospital employees, approximately 11 times the background rate for long-term care employees, 6 times the background rate for home health care workers, and double the background rate for home care employees. Based on the North Carolina data, the annual risk is

expected to be approximately 5 times the background rate. Based on the Jackson Memorial Hospital data, the annual risk is expected to be approximately 9 times the background.

Estimates of expected excess risk of TB infection for workers with occupational exposure by state are calculated by applying the excess relative risk ratios, derived from the three occupational studies, to the overall background rate of infection for each state and are presented in table V–8(a)—table V–8(c). A range of excess risk of TB infection due to occupational exposure is constructed by using the minimum and maximum estimates of excess risk among all states for each data source. These results are presented in table V–9 and table V–10 for workers in hospitals and for workers in other work settings, respectively.

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TABLE V-8(a)
Occupational Risk Estimates of TB Infection
Based on the Washington State Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	0.77 - 0.79	34 - 35
Alaska (02)	3.03 - 3.09	1.43 - 1.45	62 - 63
Arizona (04)	1.00 - 1.03	0.47 - 0.48	21 - 22
Arkansas (05)	1.67 - 1.73	0.79 - 0.81	35 - 36
California (06)	2.32 - 2.40	1.09 - 1.13	48 - 50
Colorado (08)	0.39 - 0.40	0.18 - 0.19	8 - 9
Connecticut (09)	0.68 - 0.71	0.32 - 0.33	14 - 15
Delaware (10)	1.31 - 1.34	0.62 - 0.63	27 - 28
District of Columbia (11)	3.08 - 3.18	1.45 - 1.49	63 - 65
Florida (12)	2.05 - 2.11	0.97 - 1.00	43 - 44
Georgia (13)	1.45 - 1.52	0.68 - 0.71	30 - 32
Hawaii (15)	3.43 - 3.54	1.61 - 1.66	70 - 72
Illinois (17)	1.34 - 1.39	0.63 - 0.66	28 - 29
Indiana (18)	0.50 - 0.51	0.23 - 0.24	10 - 11
Iowa (19)	0.41 - 0.42	0.19 - 0.20	9 - 9
Kansas (20)	0.58 - 0.59	0.27 - 0.28	12 - 12
Kentucky (21)	1.21 - 1.26	0.57 - 0.59	25 - 26
Louisiana (22)	1.91 - 1.95	0.90 - 0.92	39 - 40
Maine (23)	0.45 - 0.46	0.21 - 0.22	9 - 10
Maryland (24)	0.99 - 1.04	0.46 - 0.49	21 - 22
Massachusetts (25)	0.63 - 0.67	0.30 - 0.32	13 - 14
Michigan (26)	0.73 - 0.76	0.34 - 0.36	15 - 16
Minnesota (27)	0.42 - 0.44	0.20 - 0.21	9 - 9
Mississippi (28)	1.73 - 1.79	0.81 - 0.84	36 - 37
Missouri (29)	0.76 - 0.79	0.36 - 0.37	16 - 17
Montana (30)	0.47 - 0.48	0.22 - 0.23	10 - 10
Nebraska (31)	0.19 - 0.20	0.09 - 0.10	4 - 4
Nevada (32)	1.32 - 1.35	0.62 - 0.64	27 - 28
New Hampshire (33)	0.21 - 0.22	0.10 - 0.10	5 - 7
New Jersey (34)	1.44 - 1.51	0.68 - 0.71	30 - 31
New Mexico (35)	0.82 - 0.86	0.39 - 0.40	17 - 18
New York (36)	2.93 - 3.05	1.38 - 1.43	60 - 63
North Carolina (37)	1.17 - 1.22	0.55 - 0.57	24 - 25
North Dakota (38)	0.28 - 0.29	0.13 - 0.13	6 - 6
Ohio (39)	0.46 - 0.48	0.21 - 0.22	9 - 10
Oklahoma (40)	1.33 - 1.36	0.62 - 0.64	9 - 10
Oregon (41)	0.79 - 0.82	0.37 - 0.38	17 - 17
Pennsylvania (42)	0.65 - 0.69	0.31 - 0.32	14 - 14
Rhode Island (44)	0.67 - 0.70	0.31 - 0.33	14 - 15
South Carolina (45)	1.68 - 1.73	0.79 - 0.81	35 - 36
South Dakota (46)	0.66 - 0.69	0.31 - 0.33	14 - 15
Tennessee (47)	1.58 - 1.63	0.74 - 0.77	33 - 34
Texas (48)	2.26 - 2.33	1.06 - 1.10	47 - 48
Utah (49)	0.34 - 0.37	0.16 - 0.17	7 - 8
Vermont (50)	0.36 - 0.37	0.17 - 0.18	8 - 8
Virginia (51)	0.66 - 0.70	0.31 - 0.33	14 - 15
Washington (53)	0.66 - 0.69	0.31 - 0.32	14 - 14
West Virginia (54)	0.66 - 0.70	0.31 - 0.33	14 - 15
Wisconsin (55)	0.35 - 0.36	0.16 - 0.17	7 - 8
Wyoming (56)	0.55 - 0.57	0.26 - 0.27	12 - 12

TABLE V-8(b)
Occupational Risk Estimates of TB Infection
Based on the North Carolina Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	6.48 - 6.68	254 - 260
Alaska (02)	3.03 - 3.09	12.07 - 12.28	421 - 427
Arizona (04)	1.00 - 1.03	3.97 - 4.11	164 - 169
Arkansas (05)	1.67 - 1.73	6.66 - 6.90	260 - 268
California (06)	2.32 - 2.40	9.22 - 9.55	341 - 351
Colorado (08)	0.39 - 0.40	1.55 - 1.61	67 - 70
Connecticut (09)	0.68 - 0.71	2.70 - 2.81	115 - 119
Delaware (10)	1.31 - 1.34	5.23 - 5.35	210 - 215
District of Columbia (11)	3.08 - 3.18	12.27 - 12.66	426 - 436
Florida (12)	2.05 - 2.11	8.18 - 8.43	309 - 317
Georgia (13)	1.45 - 1.52	5.77 - 6.05	229 - 239
Hawaii (15)	3.43 - 3.54	13.67 - 14.10	462 - 472
Illinois (17)	1.34 - 1.39	5.32 - 5.55	214 - 221
Indiana (18)	0.50 - 0.51	1.95 - 2.05	84 - 88
Iowa (19)	0.41 - 0.42	1.64 - 1.67	71 - 73
Kansas (20)	0.58 - 0.59	2.29 - 2.35	98 - 100
Kentucky (21)	1.21 - 1.26	4.80 - 5.02	195 - 202
Louisiana (22)	1.91 - 1.95	7.58 - 7.77	290 - 296
Maine (23)	0.45 - 0.46	1.79 - 1.84	77 - 80
Maryland (24)	0.99 - 1.04	3.94 - 4.13	163 - 170
Massachusetts (25)	0.63 - 0.67	2.51 - 2.67	107 - 113
Michigan (26)	0.73 - 0.76	2.92 - 3.04	123 - 128
Minnesota (27)	0.42 - 0.44	1.68 - 1.77	73 - 77
Mississippi (28)	1.73 - 1.79	6.90 - 7.12	268 - 275
Missouri (29)	0.76 - 0.79	3.03 - 3.14	128 - 132
Montana (30)	0.47 - 0.48	1.88 - 1.93	81 - 83
Nebraska (31)	0.19 - 0.20	0.77 - 0.82	34 - 36
Nevada (32)	1.32 - 1.35	5.26 - 5.40	211 - 216
New Hampshire (33)	0.21 - 0.22	0.85 - 0.88	38 - 39
New Jersey (34)	1.44 - 1.51	5.75 - 6.01	229 - 237
New Mexico (35)	0.82 - 0.86	3.28 - 3.42	137 - 143
New York (36)	2.93 - 3.05	11.65 - 12.14	410 - 423
North Carolina (37)	1.17 - 1.22	4.66 - 4.86	190 - 196
North Dakota (38)	0.28 - 0.29	1.11 - 1.16	49 - 50
Ohio (39)	0.46 - 0.48	1.81 - 1.89	78 - 82
Oklahoma (40)	1.33 - 1.36	5.28 - 5.44	212 - 216
Oregon (41)	0.79 - 0.82	3.15 - 3.26	133 - 137
Pennsylvania (42)	0.65 - 0.69	2.60 - 2.74	111 - 116
Rhode Island (44)	0.67 - 070	2.66 - 2.77	113 - 117
South Carolina (45)	1.68 - 1.73	6.68 - 6.89	260 - 267
South Dakota (46)	0.66 - 0.69	2.64 - 2.76	112 - 117
Tennessee (47)	1.58 - 1.63	6.27 - 6.48	247 - 254
Texas (48)	2.26 - 2.33	9.01 - 9.29	334 - 343
Utah (49)	0.34 - 0.37	1.34 - 1.46	59 - 64
Vermont (50)	0.36 - 0.37	1.46 - 1.49	63- -65
Virginia (51)	0.66 - 0.70	2.64 - 2.78	112 - 118
Washington (53)	0.66 - 0.69	2.61 - 2.75	111 - 116
West Virginia (54)	0.66 - 0.70	2.64 - 2.77	112 - 117
Wisconsin (55)	0.35 - 0.36	1.39 - 1.44	61 - 63
Wyoming (56)	0.55 - 0.57	2.20 - 2.25	94 - 97

TABLE V-8(c)
Occupational Risk Estimates of TB Infection
Based on the Jackson Memorial Hospital Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	13.33 - 13.75	454 - 464
Alaska (02)	3.03 - 3.09	24.84 - 25.27	678 - 684
Arizona (04)	1.00 - 1.03	8.16 - 8.45	308 - 317
Arkansas (05)	1.67 - 1.73	13.69 - 14.20	462 - 475
California (06)	2.32 - 2.40	18.98 - 19.66	578 - 591
Colorado (08)	0.39 - 0.40	3.19 - 3.31	134 - 139
Connecticut (09)	0.68 - 0.70	5.55 - 5.78	222 - 230
Delaware (10)	1.31 - 1.34	10.75 - 11.01	385 - 392
District of Columbia (11)	3.08 - 3.18	25.24 - 26.04	683 - 695
Florida (12)	2.05 - 2.11	16.83 - 17.35	534 - 545
Georgia (13)	1.45 - 1.52	11.88 - 12.45	416 - 431
Hawaii (15)	3.43 - 3.54	28.13 - 29.01	723 - 734
Illinois (17)	1.34 - 1.39	10.95 - 11.42	391 - 404
Indiana (18)	0.50 - 0.51	4.01 - 4.21	165 - 173
Iowa (19)	0.41 - 0.42	3.36 - 3.44	141 - 144
Kansas (20)	0.58 - 0.59	4.72 - 4.83	192 - 196
Kentucky (21)	1.21 - 1.26	9.87 - 10.32	360 - 373
Louisiana (22)	1.91 - 1.95	15.60 - 15.99	507 - 516
Maine (23)	0.45 - 0.46	3.69 - 3.79	153 - 157
Maryland (24)	0.99 - 1.04	8.11 - 8.50	307 - 319
Massachusetts (25)	0.63 - 0.67	5.17 - 5.50	208 - 220
Michigan (26)	0.73 - 0.76	6.01 - 6.25	238 - 246
Minnesota (27)	0.42 - 0.44	3.46 - 3.64	145 - 151
Mississippi (28)	1.73 - 1.79	14.19 - 14.66	474 - 485
Missouri (29)	0.76 - 0.79	6.23 - 6.46	245 - 253
Montana (30)	0.47 - 0.48	3.87 - 3.96	160 - 164
Nebraska (31)	0.19 - 0.20	1.59 - 1.68	69 - 73
Nevada (32)	1.32 - 1.35	10.83 - 11.10	387 - 395
New Hampshire (33)	0.21 - 0.22	1.76 - 1.82	76 - 79
New Jersey (34)	1.44 - 1.51	11.83 - 12.36	415 - 429
New Mexico (35)	0.82 - 0.86	6.75 - 7.05	263 - 273
New York (36)	2.93 - 3.05	23.97 - 24.98	664 - 680
North Carolina (37)	1.17 - 1.22	9.60 - 9.99	352 - 364
North Dakota (38)	0.28 - 0.29	2.29 - 2.38	98 - 102
Ohio (39)	0.46 - 0.48	3.73 - 3.89	155 - 161
Oklahoma (40)	1.33 - 1.36	10.86 - 11.19	388 - 397
Oregon (41)	0.79 - 0.82	6.49 - 6.71	254 - 261
Pennsylvania (42)	0.65 - 0.69	5.35 - 5.63	214 - 224
Rhode Island (44)	0.67 - 0.70	5.47 - 5.70	218 - 227
South Carolina (45)	1.68 - 1.73	13.74 - 14.18	463 - 474
South Dakota (46)	0.66 - 0.69	5.42 - 5.68	217 - 226
Tennessee (47)	1.58 - 1.63	12.91 - 13.33	443 - 453
Texas (48)	2.26 - 2.33	18.54 - 19.10	569 - 580
Utah (49)	0.34 - 0.37	2.76 - 3.01	117 - 127
Vermont (50)	0.36 - 0.37	2.99 - 3.07	126 - 129
Virginia (51)	0.66 - 0.70	5.43 - 5.73	217 - 228
Washington (53)	0.66 - 0.69	5.38 - 5.65	215 - 225
West Virginia (54)	0.66 - 0.70	5.44 - 5.70	217 - 226
Wisconsin (55)	0.35 - 0.36	2.86 - 2.96	121 - 125
Wyoming (56)	0.55 - 0.57	4.53 - 4.64	185 - 189

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TABLE V–9.—OCCUPATIONAL RISK ESTIMATES FOR HOSPITAL EMPLOYEES [a]

Source	Overall risk/ (exposed)	Background risk based on study	Excess risk based on study (percent)	Range of excess occupational risk [d]	
				Annual	Lifetime
Washington State 1994 data	1.24/1000	0.88/1000	47	0.09–1.66	4.1–72.2
North Carolina Western Counties	[b] 5.98/1000	[d] 1.20/1000	398	0.77–14.1	34.2–472
Jackson Memorial (1991)	31.7/1000	3.5/1000	795	1.54–28.2	67.1–723

[a] Background TB infection rate ranges from 0.194 to 3.542 per 1,000 at risk for TB infection.
[b] Ajusted for 1994, i.e., 5.98=7.2*(532/641)
[c] The range reflects regional differences in TB prevalence as well as inherent uncertainty in the estimate of TB infection prevalence in the U.S., as estimated by Dr. Christopher Murray, and used in the internal calculations of annual background TB infection rate.
[d] State-wide estimate of population risk for North Carolina, shown in Table V–3(a).

TABLE V–10.—OCCUPATIONAL RISK ESTIMATES FOR OTHER WORK SETTINGS [a,b]

Type	Overall risk/ (exposed)	Background risk State-wide [c]	Excess risk based on study (percent)	Range of excess occupational risk [d]	
				Annual	Lifetime
Long-term Care	9.8/1000	0.8756/1000	1019	1.98–36.1	85–807
Home Health Care	5.06/1000	0.8756/1000	478	0.93–16.9	40.9–526
Home Care	1.86/1000	0.8756/1000	112	0.22–3.97	9.7–164

[a] Background TB infection rate ranges from 0.194 to 3.542 per 1,000 employees at risk of infection.
[b] Based on the Washington State data.
[c] Background rate for this analysis is assumed to be the same as in the case-control analysis of the Washington State hospital data (i.e. 0.8756 per 1,000 employees).
[d] The range reflects regional differences in TB prevalence as well as inherent uncertainty in the estimate of TB infection prevalence in the U.S., as estimated by Dr. Christopher Murray, and used in the internal calculations of annual background TB infection rate.

Lifetime estimates of the excess risk of TB infection were estimated based on the annual excess risk by using the formula $\{1-(1-p)^{45}\}$, where p is the annual excess risk. Lifetime excess estimates of TB infection are presented in table V–9 and table V–10. Lifetime risk estimates of developing active TB are calculated from lifetime risk estimates of TB infection assuming that, once infected, there is a 10% likelihood of progressing to active TB; these estimates are presented in table V–11 and table V–12. Further, the risk of death caused by TB is calculated from the lifetime estimates of active TB using OSHA's estimate of the TB case fatality rate (also presented in table V–11 and table V–12). The methodology used to estimate a TB case fatality rate is presented below.

TABLE V–11.—LIFETIME OCCUPATIONAL RISK ESTIMATES FOR HOSPITAL EMPLOYEES [a b c]

Source	TB infection [d]	Active disease [e]	Death caused by TB
Washington State (1994)	4.1–72.2	0.4–7.2	0.03–0.6
North Carolina Western Region	34.2–472	3.4–47.2	0.3–3.7
Jackson Memorial Hospital (Miami)	67.1–723	6.7–72.3	0.5–5.6

[a] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk.
[b] Estimates of death caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 TB cases and are estimated by multiplying the lifetime active disease rate by .07785.
[c] The ranges of risk presented in this TABLE reflect expected variance in the annual background TB infection rate by state. They are estimated based on the assumption that the annual background TB infection rate ranges from 0.194 to 1.542 per 1,000 employees at risk.
[d] Lifetime infection rate is estimated by $(1-(1-p)^{45})$, where p is the annual excess TB infection rate due to occupational exposure.
[e] Lifetime active disease rate is estimated to be 10% of lifetime infection rate.

TABLE V–12—LIFETIME OCCUPATIONAL RISK ESTIMATES FOR EMPLOYEES IN OTHER WORK SETTINGS [a b c]

Work setting	TB infection [d]	Active disease [e]	Death caused by TB
Long-term Care	85–807	8.5–80.7	0.7–6.2
Home Health Care	40.9–536	4.1–53.6	0.3–4.2
Home Care	9.7–164	1.0–16.4	0.1–1.3

[a] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk of TB infection.
[b] Estimates of death caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 cases and are estimated by multiplying the lifetime active disease rate by .07785.
[c] The ranges of risk presented in this TABLE reflect expected variance in the annual background TB infection rate by state. They are estimated based on the assumption that the annual background TB infection rate ranges from 0.194 to 3.542 per 1,000 employees at risk.
[d] Lifetime infection rate is estimated by $(1-(1-p)^{45})$, where p is the annual excess TB infection rate due to occupational exposure.
[e] Lifetime active disease rate is estimated to be 10% of lifetime infection rate.

As outlined in the Health Effects section, several possible outcomes are possible following an infection. Approximately 90% of all infections never progress to active disease. An estimated 10% of infections is expected to progress to active disease; most of these cases are successfully treated. However, a percentage of active TB cases develop further complications. Approximately 7.8% of active TB cases may take a more severe clinical course and lead to death. The TB case fatality rate was estimated using information on reported deaths caused by TB from table 8–5 of the Vital Statistics for the U.S. and cases of TB reported in CDC's TB Surveillance system for 1989 through 1991 (Exs. 7–270, 7–264). As shown in table V–13, the TB case death rate ranged from 69.94 to 89.18 per 1,000 with a 3-year average of 77.85 per 1,000 TB cases. The Agency used the 3-year average (77.85 per 1,000) for its estimate of deaths caused by TB. This estimate is in close agreement with published results from a retrospective cohort study conducted in Los Angeles County on TB cases in 1990 (Ex. 7–268). In this study, all confirmed TB cases reported in the county in 1990 were tracked and the number of deaths where TB was the direct or contributing cause was ascertained. ''Contributing cause'' was defined as a case of TB of such severity that it would have caused the death of the patient had the primary illness not caused death earlier. Of the 1,724 cases included in the study, TB was considered the cause of death or the contributing cause of death in 135 cases (78.31 per 1,000).

TABLE V–13.—TB CASE DEATH RATES FOR ADULTS (18+)

Year	Number of deaths [a]	Number of TB cases [b]	TB case death rate [c]
1991	1,700	24,307	69.94
1990	1,796	23,795	75.48
1989	1,956	21,934	89.18
3-year Average	1,817	23,345	77.85

[a] Source: Vital Statistics for the U.S., Table 8–5, (age 20+).
[b] Source: CDC, TB surveillance system, (age 18+).
[c] Rate expressed per 1,000 TB cases. Any deaths caused by TB in persons 18 or 19 years of age are not included in the numerator.

National estimates of annual and lifetime risk for TB infection, active disease and death caused by TB due to occupational exposure are computed as weighted averages of the state estimates and are presented in table V–14.

TABLE V–14.—AVERAGE OCCUPATIONAL RISK ESTIMATES [a, b] PER 1,000 WORKERS AT RISK

Work setting	Annual TB infection	Lifetime TB infection	Lifetime active TB	Death caused by TB [c]
Hospitals:				
WA	0.68	30	3.0	0.2
NC	5.7	219	22.0	1.7
JM	11.8	386	38.6	3.0
Long-term Care	14.6	448	44.8	3.5
Home Health Care	6.9	225	25.5	2.0
Home Care	1.6	69	6.9	0.5

[a] Weighted by each state's population in 1994.
[b] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk.
[c] Number of deaths caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 cases and are computed by multiplying the lifetime active disease rate by .07785.

(a) *Risk Estimates for Hospital Employees:* Logistic regression analysis of the Washington state hospital data indicated an increase in annual risk (47% above background) for employees with potential exposure to TB. For this particular analysis the control group was defined as those hospitals with no-known TB patients that are located in counties that did not report any active TB cases in 1994. However, an increased risk of 47% above background in the annual infection rate is expected to produce a range of 4 to 72 TB infections per 1000 exposed workers in a working lifetime, which could result in as many as 7 cases of active TB and approximately 1 death per 1,000 exposed workers.

Based on the survey of hospitals in North Carolina's western region, the expected overall risk due to occupational exposure is estimated to be 4 times the background rate. This results in an expected range of lifetime risk between 34 and 472 infections per 1,000 employees at risk for TB infection. Lifetime estimates of active TB cases resulting from these infections are expected to range between 3 and 47, resulting in as many as 4 deaths per 1,000 exposed employees at risk of TB infection. As done previously, the North Carolina study results were adjusted to reflect 1994 TB disease trends.

Based on the data from Jackson Memorial Hospital, the overall risk due to occupational exposure is estimated to be 8 times the background rate. This results in an expected range of lifetime risk between 67 and 723 infections per 1,000 employees at risk. Lifetime estimates of the number of active TB case per 100 exposed workers are expected to range between 7 and 72, resulting in as many as 6 deaths per 1,000 exposed employees at risk for TB infection.

In summary, table V–9 and table V–14 show that the annual occupational risk of infection is expected to range:

(a) From .09 to 1.66 with a weighted average of 0.68 per 1,000 for workplaces located in relatively low TB prevalence areas, and where TB infection measures and engineering controls are required;

(b) From 0.77 to 14.1 with a weighted average of 5.7 per 1,000 for workplaces located in areas with moderate TB prevalence and inadequate TB control programs; and

(c) From 1.54 to 28 with a weighted average of 11.8 per 1,000 for workplaces

located in high TB prevalence areas, serving high risk patients, with high frequency of exposure to infectious TB.

Similarly, the lifetime occupational risk is expected to range:

(a) From 4 to 72 with a weighted average of 30 per 1,000 for workplaces located in relatively low TB prevalence areas, and where TB infection measures and engineering controls are required;

(b) From 34 to 472 with a weighted average of 219 per 1,000 for workplaces located in areas with moderate TB prevalence and inadequate TB control programs; and

(c) From 67 to 723 with a weighted average of 386 per 1,000 for workplaces located in high TB prevalence areas, serving high risk patients, with high frequency of exposure to infectious TB.

Risk estimates derived from either study (Washington State or North Carolina) represent an overall rate of occupational risk, because both studies include PPD skin testing results from the entire hospital employee population, whereas the Jackson Memorial study addresses the occupational risk to workers where exposure to infectious TB is highly probable.

Although the exact compliance rate is not known, hospitals in Washington State have been required to implement the CDC TB guidelines with respect to engineering controls (requiring isolation rooms with negative pressure) and infection control measures (advocating early patient identification, employee training, respiratory protection, and PPD testing).

Neither the facilities in North Carolina nor Jackson Memorial had engineering controls fully implemented at the time these data were collected. Early identification of suspect TB patients has always been recommended in North Carolina. However, engineering controls in isolation rooms were either not present or did not function properly because of modifications in the physical structure of the building (i.e., isolation rooms had been subdivided using partitions, air ducts had been re-directed because of remodeling, etc.). Tuberculin skin testing was very inconsistent and sporadic. In addition, employee training and use of respiratory protection were not emphasized.

By 1991, Jackson Memorial had most of the engineering controls in place in the HIV ward (where the first outbreak took place) and in selected areas with high TB exposure, but not in the entire hospital. However, the staff training program was still being developed and respiratory protection was not always adequate. Although exposures had been greatly reduced, ''high risk'' procedures were still being performed in certain areas of the hospital without adequate engineering controls, such as the Special Immunology clinic where HIV–TB patients received pentamidine treatments. Like the hospitals in the North Carolina study, Jackson Memorial represents a working environment that serves a patient population known to have high TB prevalence. In addition, Jackson Memorial only tested employees with patient contact in areas where active TB had been detected.

(b) *Risk Estimates for Workers in Other Work Settings:* In long-term care facilities for the elderly there is also a significantly increased likelihood that employees will encounter individuals with infectious TB. Persons over the age of 65 constitute a large proportion of the TB cases in the United States. In 1987, CDC reported that persons aged 65 and over accounted for 27% (6150) of the reported cases of active TB in the U.S., although they account for only 12% of the U.S. population. Many of these individuals were infected in the past and advancing age and decreasing immunocompetence have caused them to develop active disease. In 1990 the CDC estimated that approximately 10 million people were infected with TB. As the U.S. population steadily ages, many of these latent infections may progress to active disease. Because elderly persons represent a large proportion of the nation's nursing home residents and because the elderly represent a large proportion of the active cases of TB, there is an increased likelihood that employees at long-term care facilities for the elderly will encounter individuals with infectious TB.

Similarly, there are other occupational settings that serve high-risk client populations and thus have an increased likelihood of encountering individuals with infectious TB. For example, hospices, emergency medical services, and home-health care services provide services to client populations similar to those in hospitals and thus are likely to experience similar risks.

OSHA used information from the 1994 Washington state PPD skin testing survey to estimate occupational risk for workers in long-term care, home health care, and home care. Annual estimates of excess risk for TB infection are presented in TABLE V–10 and lifetime estimates for TB infection, active TB, and death caused by occupational TB are presented in TABLE V–12.

Based on the Washington State data, the overall annual excess risk for TB infection is estimated to be 10-fold over background for workers in long-term care. This results in an expected range of lifetime risk of between 85 and 800 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases resulting from these infections range from 9 to 81 and are projected to cause as many as 6 deaths per 1,000 exposed employees at risk of TB infection. Similarly, the overall annual excess risk of TB infection for workers in home health care is estimated to be approximately 500% above background. This results in an expected range of lifetime risk of between 41 and 536 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases range from 4 to 54 per 1,000, and are projected to cause as many as 4 deaths per 1,000 exposed employees at risk of TB infection. Similarly, the overall annual excess risk of TB infection for workers in home care is estimated to be approximately 100% above background. This results in an expected range of lifetime risk of between 10 and 164 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases range from 1 to 16, and are expected to result in approximately 1 death per 1,000 exposed employees at risk of TB infection.

Clearly, employees in all three groups (long-term care for the elderly, home health care, and home care) have higher risks than hospital employees in Washington. This could be attributed, in part, to the lack of engineering controls in these work settings. That respirators may be used only intermittently may also play a role. Although workers in these three groups are encouraged by local health authorities to use respiratory protection while tending to a suspect TB patient, the actual rate of respirator usage is difficult to ascertain. A third factor that may contribute to higher risk in these work settings is delayed identification of suspect TB patients due to confounding symptoms presented by the individuals. For example, many long-term care residents exhibit symptoms of persistent coughing from decades of smoking. Consequently, an individual in long-term care with a persistent cough may be infectious for several days before he or she is identified as having suspected infectious TB.

Qualitative Assessment of Risk for Other Occupational Settings

The quantitative estimates of the risk of TB infection discussed above are based primarily upon data from hospitals and selected other health care settings. Data from hospitals and certain health care settings were selected because OSHA believes that these data

represent the best information available to the Agency for purposes of quantifying the occupational risks of TB infection and disease. However, as discussed above, it is their exposure to aerosolized *M. tuberculosis* that places these workers at risk of infection and not factors unique to these particular kinds of health care activities. Thus, OSHA believes that the risk estimates derived from hospitals and selected other work settings can be used to describe the potential range of risks for other health care and other occupational settings in which workers can reasonably anticipate frequent and substantial exposure to aerosolized *M. tuberculosis.*

In order to extrapolate the quantitative risk estimates calculated for hospital employees and other selected health care settings, OSHA, as a first step, identified risk factors that place employees at risk of exposure. Some amount of exposure to TB could occur in any workplace in the United States. TB is an infectious disease that occurs in the community and thus, individuals may bring the disease into their own workplace or to other businesses or work settings that they may visit. However, there are particular kinds of work settings where risk factors are present that substantially increase the likelihood that employees will be frequently exposed to aerosolized *M. tuberculosis.* First among these factors is the increased likelihood of exposure to individuals with active, infectious TB. Individuals who are infected with TB have a higher risk of developing active TB if they are (1) immunocompromised (e.g., elderly, undergoing chemotherapy, HIV positive), (2) intravenous drug users, or (3) medically underserved and of generally poor health status (Exs. 6–93 and 7–50). Thus, in work settings in which the client population is composed of a high proportion of individuals who are infected with TB, are immunocompromised, are intravenous drug users or are of poor general health status, there is a greatly increased likelihood that employees will routinely encounter individuals with infectious TB and be exposed to aerosolized *M. tuberculosis.* A second factor that places employees at high risk of exposure to aerosolized *M. tuberculosis* is the performance of high-hazard procedures, i.e., procedures performed on individuals with suspected or confirmed infectious TB where there is a high likelihood of the generation of droplet nuclei. A third factor that places employees at risk of exposure is the environmental conditions at the work setting. Work settings that have overcrowded conditions or poor ventilation will facilitate the transmission of TB. Thus, given that a case of infectious TB does occur, the conditions at the work setting itself may promote the transmission of disease to employees who share airspace with the individual(s) with infectious TB.

The second step in extrapolating the quantitative risks is to identify the types of work settings which have some or all of the risk factors outlined above. Once these work settings have been identified, OSHA believes that it is reasonable to assume that the quantitative risk estimates calculated for hospitals and other selected health care settings can be used to describe the risks in the identified work settings.

Correctional Facilities

Employees in correctional facilities or other facilities that house inmates or detainees have an increased likelihood of frequent exposure to individuals with infectious TB. Many correctional facilities have a higher incidence of TB cases in comparison to the incidence in the general population. In 1985, the CDC estimated that the incidence of TB among inmates of correctional facilities was more than three times higher than that for nonincarcerated adults aged 15–64 (Ex. 3–33). In particular, in states such as New Jersey, New York, and California, the increased incidence of annual TB cases in correctional facilities ranged from 6 to 11 times greater than that of the general population for their respective states (Exs. 7–80 and 3–33). A major factor in the increased incidence of TB cases in correctional facilities is the fact that the population of correctional facilities is over-represented by individuals who are at greater risk of developing active disease, e.g., persons from poor and minority groups who may suffer from poor nutritional status and poor health care, intravenous drug users, and persons infected with HIV. Similarly, certain types of correctional facilities, such as holding facilities associated with the Immigration and Naturalization Service, may have inmates/detainees from countries with a high incidence of TB. For foreign-born persons arriving in the U.S., the case rate of TB in 1989 was estimated to be 124 per 100,000, compared to an overall TB case rate of 9.5 per 100,000 for the U.S. (Ex. 6–26). Moreover, in the period from 1986 to 1989, 22% of all reported cases of TB disease occurred in the foreign-born population. Given the increased prevalence of individuals at risk for developing active TB, there is an increased likelihood that employees working in these facilities will encounter individuals with infectious TB. In addition, environmental factors such as overcrowding and poor ventilation facilitate the transmission of TB. Thus, given that a case of infectious TB does occur, the conditions in the facility itself promote the transmission of the disease to other inmates and employees in the facility who share airspace.

As discussed in the Health Effects section, a number of outbreak investigations (Exs. 6–5, 6–6) have shown that where there has been exposure to aerosolized *M. tuberculosis* in correctional facilities, the failure to promptly identify individuals with infectious TB and provide appropriate infection control measures has resulted in employees being infected with TB. These studies demonstrate that, as in hospitals or health care settings, where there is exposure to aerosolized TB bacilli and where effective control measures are not implemented, exposed employees are at risk of infection. Thus, estimates based on the risk observed among employees in hospitals and in selected other work settings that involve an increased likelihood of exposure can be appropriately applied to employees in correctional facilities.

Recently, scientists at NIOSH have completed a prospective study of the incidence of TB infection among New York State correctional facilities employees (Ex. 7–288). This study is the first prospective study of TB infection among employees in correctional facilities in an entire state. Other studies have reported on contact investigations, which seek to identify recent close contacts with an index case and determine who might subsequently have been infected. Studies based on contact investigations have the advantage of a good definition of potential for exposure and they serve to identify infected persons for public health purposes. On the other hand, prospective studies of an entire working group have the advantage of covering the entire population potentially at risk, of considering all inmate cases simultaneously as potential sources of infection, and, most importantly, of permitting the calculation of incidence rates and risk attributable to occupational exposure.

Following an outbreak of active TB among inmates that resulted in transmission to employees in 1991, the state of New York instituted a mandatory annual tuberculin skin testing program to detect TB infection among employees. The authors used data from the first two years of testing to estimate the incidence of TB infection

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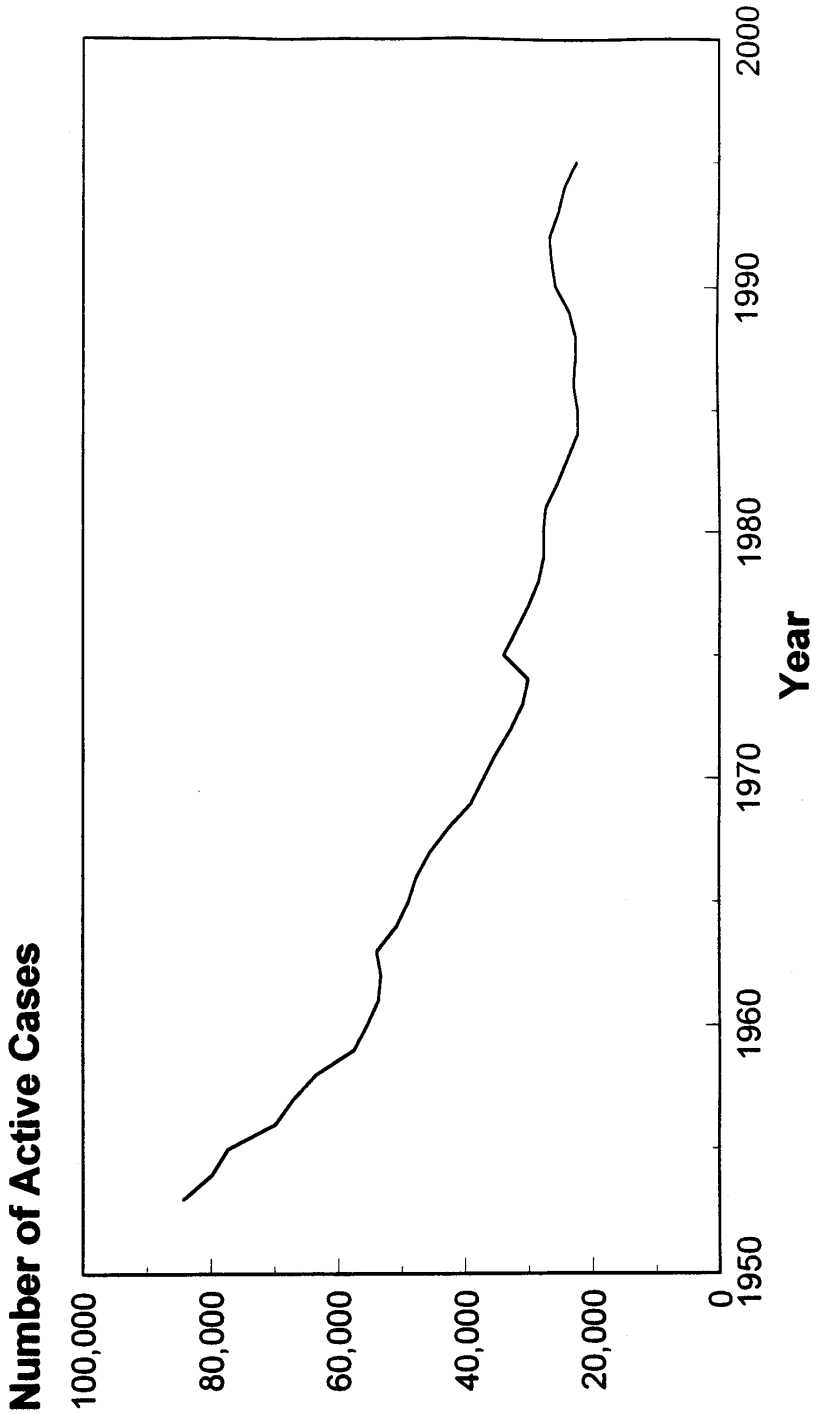
Figure VII-1. Cases of Tuberculosis by Year (1953-1995)



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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

oil), and P (oil proof). Given these categories, a type N95 respirator would meet or exceed the filter efficiency performance criteria set forth in the CDC guidelines which state that a respirator appropriate for use in protecting against transmission of tuberculosis must be able to filter particles 1 micron in size in the unloaded state with a filter efficiency of ≥95%, given flow rates up to 50 liters per minute (Ex. 4B). The underlying reasoning for the acceptability of type N95 respirators is that their filter efficiency of 95% for a 0.3 micron particle will exceed 95% filtering efficiency for a particle three times as large (i.e., 1 micron). Also, the Agency assumes that oil aerosols are not likely to be found in the work settings covered by the standard, and therefore, that the use of a category N respirator would be sufficient. However, if oil aerosols are present, the employer would be expected to consider this when selecting the category of respirator to be used in his or her workplace.

OSHA is permitting the employer to select either a HEPA respirator certified under 30 CFR part 11 or a respirator certified under 42 CFR part 84, since particulate respirators certified under both of these regulations are currently on the market. HEPA respirators are the only nonpowered particulate respirators certified under 30 CFR part 11 that meet the CDC guidelines filtration criteria. However, applications for certification of nonpowered particulate respirators under 30 CFR part 11 are no longer being accepted by NIOSH. Therefore, dwindling stocks of HEPA respirators certified under that regulation will eventually lead to their unavailability, and employers will of necessity be selecting respirators from those approved under 42 CFR part 84.

Paragraph (f)(4)(i) states that the employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any conditions that prevent such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or facial hair that interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal. Paragraph (f)(4)(ii) requires the employer to assure that each employee who wears corrective glasses or goggles wears them in such a manner that they do not interfere with the seal of the facepiece to the face of the wearer. Tight-fitting facepiece respirators rely on a good face-to-facepiece seal in order to achieve effective protection. Therefore, the employer must not allow employees to wear such respirators with conditions that prevent such a seal. Several studies support the prohibition of facial hair that comes between the sealing surface of the facepiece and the face (Exs. 7–243, 7-242, 7–182). A study by Skretvedt and Loschiavo found that bearded subjects wearing half-mask respirators had a median face seal leakage 246 times greater than clean shaven subjects. They go on to state:

> Even though a number of bearded individuals did obtain fit factors above OSHA's minimum requirement for half-mask respirators, they all failed the qualitative fit test. No relationship was found between the length, shape, density and texture of beards and the amount of face seal leakage. Therefore, the only way to identify bearded negative-pressure respirator wearers obtaining fit factors above OSHA's minimum requirements would be by performing a quantitative fit test on them. However, even if quantitative fit tests are performed on all bearded individuals, another problem must be faced. The drop in the fit factor experienced when a beard is present is of such magnitude that no confidence can be placed in the protection the respirator will provide in the workplace or in future donnings. All respirator users experience variability from one donning to the next. This fit variability from donning to donning occurs due to changes in strap tension, positioning on the face, and a host of other variables. Donning-to-donning fit variability for bearded individuals will be even greater since additional variables will be introduced. A beard is a dynamically changing thing. The hair length constantly changes as well as the orientation of the hair in the sealing surface. Beards also accumulate moisture, natural oils, and debris from the workplace. Even though a percentage of bearded respirator wearers obtain fit factors slightly above OSHA's minimum requirements, the tremendous drop in fit factor resulting from the presence of a beard is such that the safety factor necessary to accommodate the variability of fit no longer exists. In summary, although bearded individuals may be able to achieve fit factors above OSHA's minimum requirements during a specific quantitative fit test, the drop in protection caused by a beard coupled with the large fit variability from donning to donning makes it quite likely that the individual will not obtain the minimum required protection in the workplace. (Ex. 7–243)

Therefore, while a bearded respirator wearer may be able to obtain a satisfactory fit on a particular occasion, one cannot assume that the individual can reliably be expected to achieve that same protection level each time the respirator is used. Beards grow and change daily. Each time a respirator is donned there is fit variability. Such variability in face seal is greatly increased for bearded workers. This large variability in fit means that a reliable seal cannot be reasonably expected. This provision should not be construed as a blanket prohibition on beards among respirator wearers. There are other types of respiratory equipment such as hoods, helmets and suits that can be worn by employees with beards, since they do not rely upon a tight facepiece fit. In addition, this provision refers to facial hair that interferes with the facepiece seal rather than simply growth of beard or sideburns. It is the interference with the facepiece seal that is the concern, not the presence of facial hair. Other conditions such as the absence of normally worn dentures, facial scarring and cosmetic surgery change the geometry of the face, thereby changing the ability of the respirator wearer to achieve a facepiece seal. Facepiece seal may also be compromised when headgear, temple pieces and nose pieces of glasses, the edges of goggles and so forth project underneath the respirator's sealing surface. Both of the above provisions are intended to eliminate or minimize conditions that jeopardize face-to-facepiece seal and could permit leakage of outside air into the facepiece.

Paragraph (f)(4)(iii) states that disposable respirators must be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use. It is not expected that the filter media of respiratory protective devices would become occluded with particulates in the work settings covered by this standard. However, if excessive resistance is noted, the respirator must be discarded. Also, such respirators must be structurally sound in order to provide a proper face seal and maintain their effectiveness. Whenever physical damage occurs (e.g., the respirator is crumpled or torn; the flexible face seal is damaged; a head strap is broken), effective functioning cannot be assured and the respirator must be replaced. In addition, other conditions may render the respirator unsuitable for use (e.g., the respirator may become contaminated with blood), thereby requiring discard.

In view of the types of activities carried out and the environmental conditions encountered in the work settings covered by this standard, OSHA is proposing to allow the multiple use of disposable respirators. However, this action should in no way be construed as setting a precedent for the use of disposable respirators in any other OSHA standards or in how OSHA views multiple use of disposable respirators in other work settings. OSHA requests comment on the approach taken in this proposal toward the reuse of disposable respirators.

Paragraph (f)(4)(iv) requires the employer to assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. In performing the fit check, the procedures in Appendix B or other procedures recommended by the respirator manufacturer that provide equivalent protection to the procedures in Appendix B must be used. This provision is supported by a recent study by Meyers et al. that concluded:

> * * * for wearers of respirators that have been properly fit by a recognized fit test, conducting fit checks according to the manufacturer's instructions can be a useful tool for more consistently maintaining the quality of respirator donning. (Ex. 7–233)

The use of such seal checks are a way of helping to assure that attention is paid to obtaining an adequate facepiece seal each time a respirator is used.

The standard requires, under paragraph (f)(4)(v), that respirators be immediately repaired, or discarded and replaced when they are no longer in proper working condition. Examples of these changes in condition would be that a strap has broken, the respirator has lost its shape, or the face seal can no longer be maintained. As discussed above, respirators must be in good working condition in order to function effectively. Therefore, it is imperative that they not be used if they have been impaired in any way. The respirator manufacturers can supply replacement parts for damaged portions of their elastomeric respirators. Disposable respirators cannot be repaired and must be discarded when damaged.

Paragraph (f)(4)(vi) stipulates that the employer shall permit each employee to leave the respirator use area as soon as practical to: (A) change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or (B) wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use. This provision encourages and facilitates the proper use of respirators by employees by authorizing employees to take specific actions to assure the effective functioning of their respirators. This provision is consistent with requirements in other health standards (e.g., Lead, 29 CFR 1910.1025; Cadmium, 29 CFR 1910.1027).

Considering the health problems that may be exacerbated with respirator use and their associated detrimental effects on an employee, the proposal states in paragraph (f)(4)(vii) that each employee required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section to determine whether any health conditions exist that could affect the employee's ability to wear a respirator. In addition, paragraph (f)(4)(viii) states that no employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to continue to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be in accordance with paragraph (g)(5)(iii) under Medical Removal Protection of this section.

Common health problems that could interfere with respirator use include claustrophobia (an intolerance of feeling enclosed and a subjective feeling of breathing difficulty), chronic rhinitis, nasal allergies that would necessitate frequent removal of the respirator to deal with nasal discharges, and chronic sinusitis. In addition, difficulties with the use of respirators may arise in employees with respiratory or cardiac diseases. Respiratory diseases include chronic obstructive pulmonary disease, emphysema, asthma, and moderate to severe pneumoconiosis. Cardiac or cardiorespiratory diseases that may affect respirator wear include any type of congestive heart disease, other ischemic heart diseases, and hypertension.

As discussed further under paragraph (g)(5)(iv), Medical Surveillance, of this section, employees who are removed from work due to the inability to wear a respirator are afforded certain medical removal protection relative to retention of earnings, seniority, rights and benefits. The Agency believes that these provisions will encourage all employees, including those experiencing difficulty with respirator use, to participate in the Medical Surveillance Program and will minimize an employee's fear of losing his or her job due to the possible inability to wear a respirator.

Paragraph (f)(5)(i) requires the employer to perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in Appendix B of this section.

Quantitative fit testing is an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the facepiece. One method of accomplishing this assessment utilizes a procedure whereby the level of penetration of a test agent of a known concentration is measured inside the facepiece of the respirator. In this quantitative fit test procedure, the respirator is worn in a stable test atmosphere containing a suitable challenge agent. The adequacy of fit is determined by measuring the actual levels of the challenge agent, both outside and inside the facepiece of the respirator. This provides a quantitative assessment of the fit (the fit factor). Fit testing allows the employer to continue testing different facepieces until a properly fitting respirator is identified and selected for the employee. Quantitative fit testing requires the use of moderately sophisticated testing equipment and is more expensive to perform than qualitative fit testing, which may reduce its availability in some work sites. Also, testing services may not be available in all parts of the country to provide quantitative fit testing services for small businesses.

Qualitative fit testing does not provide a numerical measure of the quality of the fit but simply determines whether a respirator fits or not. The outcome of the test is simply a pass or fail result. Qualitative fit testing involves the detection of a gas, vapor, or aerosol challenge agent through subjective means such as odor, taste, or nasal irritation. If the challenge agent's presence is detected, the respirator fit is considered to be inadequate. Qualitative fit testing is more subjective than quantitative testing because it depends on the individual's ability to detect the test agent.

OSHA believes that while quantitative fit testing has some advantages, qualitative fit testing conducted in accordance with the protocols described in Appendix B of this section can generally accomplish the intent of the standard, which is to assure that each employee is assigned and wears a respirator that provides a proper fit.

Paragraph (f)(5)(ii) states that the employer shall assure that each employee who must wear tight-fitting respirator passes a fit test: (A) at the time of initial fitting; (B) whenever changes occur in the employee's facial characteristics that affect the fit of the respirator; (C) whenever a different size or make of respirator is used; and (D) at least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, indicates that the annual

fit test of the employee is not necessary. This frequency of fit testing is necessary to assure that factors that may affect the proper fit of a respirator are detected and necessary adjustments are performed to assure the integrity of the faceseal. For example, the fit of respirators is not standardized among manufacturers. Fit testing would be required, therefore, whenever a different size or make of respirator is used. In addition, a change in an employee's facial structure can compromise a respirator's faceseal. Examples of such changes include loss of weight, cosmetic surgery, facial scarring, and the installation of dentures or the absence of dentures that are normally worn by the individual. Therefore, fit testing is required when any facial changes, such as those mentioned above, occur.

Requiring annual fit testing, unless the annual determination by the physician or other licensed health care professional indicates that the annual fit test is not necessary, assures that factors that could affect respirator fit are detected and the employee's respirator is adjusted or replaced as necessary. It is OSHA's intent in this provision that each employee be evaluated annually for respirator fit. This can be accomplished through either an actual fit test or through a person-to-person evaluation consisting of a questionnaire and personal observation by the evaluator carried out under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section. It should be noted that an annual determination of respirator fit is required, either through fit testing or the person-to-person evaluation. The employer may use the determination of the need for the annual fit test in lieu of an annual fit test if that determination indicates that a fit test is not necessary.

One of the criteria that must be satisfied when selecting respirators is a faceseal leakage of 10% or less. OSHA considers any respirator that passes a qualitative fit test to meet this criteria. However, quantitative fit testing necessitates that a particular numerical value be achieved. Therefore, paragraph (f)(5)(iii) requires that when quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber. This value corresponds to a faceseal leakage of 10% or less.

In order to assure that continuing protection is achieved by reusable and powered air purifying respiratory protective devices, it is necessary to establish and implement proper maintenance and care procedures. A lax attitude toward this part of the respiratory protection program will negate successful selection and fit because the devices will not deliver the assumed protection unless they are kept in proper working order. A basic program for assuring proper respirator function would contain procedures for cleaning, inspection, repair, and replacement of respirators used in the workplace.

Paragraph (f)(6)(i) requires that the employer clean and disinfect the respirators using the manufacturer's recommended procedures at the following intervals: (A) as necessary for respirators issued for the exclusive use of an employee; and (B) after each use for respirators issued to more than one employee. Respirators that are not cleaned and disinfected can cause skin irritation and dermatitis. When more than one employee uses the same respirator, cleaning and disinfecting after each use provides the additional benefit of minimizing the respirator's role as a vehicle for spreading infections (e.g., skin, respiratory) between employees.

In order to assure continued respirator reliability, they must be inspected on a regular basis. Therefore, paragraph (f)(6)(ii) requires that respirators be inspected before each use and during cleaning after each use. As stipulated in paragraph (f)(6)(iii), such inspections must include: (A) a check of respirator function, tightness of connections and condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and (B) a check of the rubber or elastomer parts for pliability and signs of deterioration. In this way, the employer can assure that the respirator is functioning as intended, is able to be adjusted by the user, will not allow leakage through cracks or breaks in the respirator, and is pliable enough to achieve a proper faceseal.

The standard also contains provisions regarding those respirators that are found to be deficient upon inspection. Paragraph (f)(6)(iv) states that respirators that fail to pass inspection must be removed from service and repaired or adjusted in accordance with the following: (A) repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer and by persons appropriately trained to perform such operations; (B) only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and (C) reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for adjustment or repair. It is self-evident that repairs to respirators should only be performed by trained individuals, using parts designed for the specific respirator under repair (not all respirator designs are identical), and that the individual should not attempt repairs that he or she is not qualified to undertake or which are not recommended by the manufacturer.

Another important aspect of assuring appropriate respirator function is proper storage. Therefore, paragraph (f)(6)(v) stipulates that the employer assure that respirators are stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, damaging chemicals and that prevents deformation of the facepiece or exhalation valve. Proper storage, of both new respirators and those already in service, assists in maintaining appropriate respirator function by minimizing conditions that may cause deterioration of the respirator or filter, interfere with filter efficiency, change faceseal geometry, and prevent sealing of valves against inhalation of contaminated air.

As discussed previously, OSHA accepts those respirators certified by MSHA and NIOSH. Therefore, paragraph (f)(7)(i) requires that filters, cartridges, and canisters used in the workplace are properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service. The employer must assure that the existing NIOSH approval label on a filter, cartridge, or canister is not intentionally removed, obscured, or defaced while it is in service in the workplace, as required by paragraph (f)(7)(ii) of this section.

Paragraph (f)(8) requires the employer to review the overall respiratory protection program at least annually, and conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The reason an employer must conduct an annual review and inspections as necessary is because respirators are utilized as supplemental and, in some instances, sole protection to prevent transmission of infectious TB. Therefore, it is of primary importance to assure proper implementation of the program. The review of the program must include an assessment of each element required under paragraph (f)(2) of this section. Once the respiratory protection program is implemented, the employer retains responsibility for detecting and

addressing problems that arise. While the written respiratory protection program is required to be reviewed and updated under paragraph (f)(2)(iii) of the standard, the overall review requires that the employer evaluate actual implementation in the workplace. Consequently, this provision stipulates inspections of the workplace and an assessment of each element required under paragraph (f)(2) of this section to assure proper implementation of the program.

OSHA believes that the proposed provisions regarding respirators are both appropriate and justified. OSHA seeks comments and data on all aspects of the proposed respirator requirements.

Paragraph (g) Medical Surveillance

(1) General

The purpose of this section is early detection and prevention of disease through employee medical histories and physical examinations, TB skin testing, medical management and follow-up of exposure incidents and skin test conversions, and medical removal of employees with suspected or confirmed infectious TB. These requirements are designed to ensure early detection of TB infections and disease by providing appropriate medical examinations to enable identification of infection or disease and to minimize the spread of TB to other employees in the workplace. Additionally, there are requirements in this section to assure that employees required to wear respiratory protection are evaluated to determine their ability to wear a respirator and advised about the need for annual fit testing. The needs of employees who have health conditions that might require special attention are also addressed (e.g., anergy testing, more frequent screening, or further medical examinations to diagnose TB).

Paragraph (g)(1) calls for medical surveillance to be provided for each employee who has occupational exposure, as defined in this standard. Occupational exposure may result in TB infection and the subsequent development of TB disease. Paragraphs (c)(1)(i, ii), (exposure determination) require the employer to identify employees with occupational exposure in the facility. These employees must be offered medical surveillance.

OSHA believes that early detection and management of exposed employees helps prevent severe illness and death. According to CDC's 1994 edition of the Core Curriculum on Tuberculosis (Ex. 7–93), approximately ten percent of the persons infected will develop active TB disease at some point in their lives (Exs. 4B, 7–50, 7–93). Five per cent of those infected develop disease within the first two years following infection and another five percent develop disease later in their lives. Immunosuppressed persons are at a considerably greater risk of developing active disease following a TB infection. For example, individuals infected with HIV and TB have been estimated to have a 8–10% risk per year of developing active disease (Ex. 7–50). However, according to the American Thoracic Society:

> Clinical trials have shown that daily isoniazid preventive therapy for 12 months will reduce the risk of developing tuberculosis in infected persons by about 70 percent and in over 90 percent of patients who are compliant in taking the medications. (Ex. 5–80)

Most infected people have a positive reaction to the TB skin test within 2–10 weeks after exposure. Consequently, early detection of newly infected workers is critical as it permits early initiation of appropriate therapy and results in a decrease in morbidity and mortality.

Paragraph (g)(1)(ii) requires that information about the signs and symptoms of pulmonary tuberculosis disease, a medical history, a physical examination, TB skin testing, medical management and follow-up, and if indicated, other related tests and procedures and medical removal protection if the employee develops infectious TB, be provided to each employee in work settings described in paragraph *(a) Scope* who sustains an ''exposure incident.'' This provision is applicable when the employee has not been categorized as having occupational exposure in the employer's Exposure Control Plan. OSHA recognizes that there may be times when employees who are not ''reasonably anticipated'' to have occupational exposure to TB may be exposed, (e.g., if engineering controls break down or an individual with infectious tuberculosis is unidentified during intake procedures). Employees exposed under such circumstances incur the risk of TB infection and subsequent disease (Ex. 7–93) as a result of their work duties. OSHA includes this provision so that these employees are provided protection.

Paragraph (g)(1)(iii)(A) requires the employer to provide all medical surveillance at no cost to the employee. This is consistent with OSHA policy. Providing services at no cost to the employee is an important factor in successful workplace health and safety programs because it encourages employee participation in medical surveillance programs.

Paragraph (g)(1)(iii)(B) requires that all medical surveillance be provided at a reasonable time and place for the employee. Convenience of these procedures increases the likelihood of employee participation in the program. This helps assure that employees receive the full benefits provided by the standard. OSHA recognizes the need for this provision and has included it in other standards (e.g., Ethylene Oxide, 29 CFR 1910.1047; Asbestos, 29 CFR 1910.1001; and Bloodborne Pathogens 29 CFR 1910.1030).

Paragraph (g)(1)(iii)(C) states that all medical surveillance is required to be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA has included in paragraph *(j) Definitions*, a description of the licensed health care professional. Such an individual is a physician or other health care professional who holds a license enabling her or him to independently provide or be delegated the responsibilities to provide some or all of the health care services required by this paragraph. In several states, nurse practitioners may be licensed to independently perform or supervise the evaluations and procedures required by this paragraph. In such cases, the requirements of this standard can be accomplished by those practitioners. In addition, where registered nurses are licensed to perform or supervise some of the requirements of this standard, those requirements can be accomplished by those professionals.

Paragraph (g)(1)(iii)(D) requires that medical surveillance procedures be provided according to recommendations of the CDC, current at the time these procedures are performed, except as specified by this paragraph (g). In other words, employers must comply with paragraph (g), and with the most current CDC recommendations in providing medical surveillance. OSHA has set forth what an employer must do to prevent or minimize occupational exposure in the employer's workplace. However, CDC, an agency of the U.S. Public Health Service (USPHS), follows the epidemiology of *M. tuberculosis* and periodically revises and updates its guidelines and recommendations to reflect changes in the diagnosis and treatment of TB. OSHA believes that in addition to meeting the requirements of paragraph (g), it is appropriate to follow CDC recommendations, which address screening, medical evaluations, TB skin test procedures and follow-up (e.g., the administration and interpretation of skin tests).

OSHA recognizes the dynamic nature of medical knowledge relating to

tuberculosis and notes that CDC recommendations current at the time of the standard's publication may differ from recommendations at some future time when an employee evaluation takes place. Knowledge about tuberculosis is expanding. For example, the medical response to HIV/AIDS as related to tuberculosis continues to evolve. These are the reasons why OSHA has not simply required the employer to comply with a particular CDC guideline. OSHA believes that incorporating the CDC recommendations into the standard by reference enhances the quality of medical surveillance. This assures that employees are provided the most current and effective evaluation and treatment. Furthermore, the CDC recommendations provide consistency with regularly updated medical science and health care practice. A similar provision was included in the Bloodborne Pathogens standard 29 CFR 1910.1030 and met with widespread acceptance from the regulated community. The CDC recommendations cover the specific details of the medical protocols.

Paragraph (g)(1)(iv) requires that all laboratory tests be performed by an accredited laboratory. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. (For an explanation of ''accredited laboratory'' see paragraph *(j) Definitions* below). This accreditation process is required to assure a measure of quality control so that employees receive accurate information concerning their laboratory tests. The accreditation requirement assures long-term stability and consistency among laboratory test procedures and interpretations of results. OSHA recognizes the need for this requirement and has included it in other standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

(2) Explanation of Terms

This paragraph explains the terms used in paragraph *(g) Medical Surveillance.* Paragraphs (g)(2)(i) to (g)(2)(vii) include explanations of the ''medical history'', the ''physical examination (with emphasis on the pulmonary system, signs and symptoms of infectious tuberculosis, and factors affecting immunocompetence)'', ''TB skin testing'', the ''face-to-face determination of ability to wear a respirator and need to be re-fit tested'', ''medical management and follow-up'', ''other related procedures or tests determined to be necessary'', and ''Medical Removal Protection''. The applications section, paragraph (g)(3), describes what must be provided and at what time.

Paragraph (g)(2)(i) describes a medical history, during which the examiner questions the employee in order to gather information on the employee's pulmonary system, TB exposure, vaccination, testing and disease status and factors affecting immunocompetence. A medical history questionnaire may be used as a starting point for this discussion. OSHA believes that a medical history is essential for interpreting the TB skin test results, which are also required by this paragraph (g). The CDC Core Curriculum states:

> TB skin testing is a useful tool, but is not perfect. Several factors can affect the skin test reaction: for example, infection with mycobacteria other than *M. tuberculosis* and vaccination with BCG. These factors can lead to false-positive reactions * * * Other factors, such as anergy, can lead to false-negative reactions. (Ex. 7–93).

Therefore, the medical history is used to assist in interpreting the TB skin test results. The medical history also provides information regarding the employee's potential for increased risk if exposed to tuberculosis. Based on this information, discussions between the employee and the examiner regarding the employee's increased risk can assist the employee in decision-making.

Paragraph (g)(2)(ii) describes the physical examination. The physical examination is to emphasize the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence. Such an examination assists the examiner in detecting evidence of active disease (e.g., rales), differentiating TB disease from other causes of cough or other signs/symptoms associated with TB disease, and ascertaining whether signs are present that are compatible with an immunocompromising health condition. The physical examination is also required when an employee has signs or symptoms of TB or after a TB skin test conversion and at other times, if indicated.

That the pulmonary system is emphasized in both the medical history and physical examination assures that the employee is evaluated with specific attention to the most common site of infectious TB. Although extrapulmonary tuberculosis can occur (e.g., in bone, meninges of the brain, and draining abscesses), it is not usually a source of infection for others. The language ''with emphasis on the pulmonary system'' is used to indicate that while the history and physical examinations evaluate the health of the patient as a whole, particular emphasis should be placed on the pulmonary system.

Paragraph (g)(2)(iii) explains the required TB skin testing. TB skin testing is the cornerstone for early detection of TB transmission among exposed workers. The American Thoracic Society notes that:

> Although currently available TB skin tests are substantially less than 100% sensitive and specific for detection of infection with *M. tuberculosis,* no better diagnostic methods have yet been devised. (Ex. 5–4)

The TB skin test is an important tool that is useful in identifying employees who may be eligible for appropriate, early treatment; initiating contact investigations; and evaluating the effectiveness of the facility's control program. The requirement for TB skin testing is supported by AHA (Exs. 7–61, 7–29), APIC (Ex. 7–30), AIHA (Ex. 7–170) and the CDC 1994 Core Curriculum which states, ''TB screening should be done in groups for which rates of TB are substantially higher than the general population.'' [Ex. 7–93]. In this document, CDC specifically mentions screening for health care workers, staff of long term care facilities, correctional facilities, hospices, drug treatment centers, and nursing homes.

Paragraph (g)(2)(iii) describes the requirement for TB skin testing. TB skin testing, which only applies to employees whose TB skin test status is not known to be positive, includes anergy testing if indicated, and consists of an initial 2-step protocol for each employee who has not been previously skin tested and/or for whom a negative test in the past 12 months cannot be documented. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be used to fulfill the skin testing portion of the initial medical surveillance requirements. For example, if an employer has a new or existing employee for whom: (1) a TB skin test has not previously been performed, or (2) a negative skin test result within the past 12 months that cannot be documented, the employer is required to provide an initial two-step skin test for the employee. Conversely, if the employer can document a negative skin test result from a test performed on the employee within the past 12 months, that test can be used to fulfill the initial skin testing requirement of this section. Subsequent periodic retesting of the employee is to be performed in accordance with paragraph (g)(3), as discussed below.

It is important for the employer to determine the current TB skin test status

of employees prior to their initial assignment to a job with occupational exposure. This ''baseline'' status can then be used to evaluate changes in the employees' TB skin test.

In their 1992 guidelines, the American Thoracic Society recommended the following:

> Individuals at high risk for TB should have a TB skin test at least once to assess their need for preventive therapy and to alert the health care providers of those with positive skin tests of this medical problem. In institutional settings, baseline information on the TB skin test status of staff and residents is a means of identifying candidates for preventive therapy as well as determining whether transmission of TB is occurring in the facility. For this reason, TB skin testing upon employment or upon entry should be mandatory for staff and residents * * * (Ex. 5–80)

Previous BCG vaccination is not a contraindication for skin testing. In its 1994 guidelines, the CDC states:

> During the pre-employment physical or when applying for hospital privileges, HCWs who have the potential for exposure to *M. tuberculosis* [sic], including those with a history of BCG vaccination, should have baseline PPD skin testing performed * * *
>
> BCG vaccination may produce a PPD reaction that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis.* For a person who was vaccinated with BCG, the probability that a PPD test reaction results from infection with *M. tuberculosis* increases (a) as the size of the reaction increases, (b) when the person is a contact of a person with TB, (c) when the person's country of origin has a high prevalence of TB, and (d) as the length of time between vaccination and PPD testing increases. For example, a PPD test reaction of ≥10 mm probably can be attributed to *M. tuberculosis* in an adult who was vaccinated with BCG as a child and who is from a country with a high prevalence of TB. (Ex. 4B)

CDC does not state that BCG vaccination negates the need for baseline and periodic skin testing but does state that skin tests on vaccinated individuals need to be interpreted carefully. OSHA's proposed rule is consistent with the CDC Guidelines on this point. PPD testing is thus not contraindicated for BCG vaccinated employees; however, such prior vaccination does mean that other factors, such as the age of the employee and the extent of induration, must be considered in interpreting the results.

The purpose of performing a *two-step test* is to correctly identify the baseline TB skin test status of those employees who are infected with TB but whose sensitivity to the tuberculin testing material may have waned over the years. This procedure enhances the proper interpretation of subsequent positive TB skin test results and is based upon current CDC and American Thoracic Society recommendations (Exs. 5–80, 6–15, 7–52, 7–93, 7–169).

Two-step testing requires an employee to be tested initially and, if the test results are negative, to be tested again within 1–3 weeks. This second test stimulates or ''boosts'' the body's response to the testing material and results in a more valid reaction. For example, an employee who has not been recently tested but who is infected with TB from an earlier exposure may fail to respond to this current test because his or her immune response has waned over time. However, a second test of this employee will produce a positive TB skin test that more accurately reflects his or her true TB skin test status. Thus, the initial use of a two-step testing procedure ensures that the baseline TB skin test is an accurate reflection of the employee's TB status and will reduce the likelihood of misinterpreting a ''boosted'' reaction on subsequent tests as a conversion. Two-step testing is also appropriate for individuals who have been BCG vaccinated, since these individuals can exhibit a boosted reaction. Therefore, two-step testing of BCG vaccinated individuals can be used to determine their baseline status, although the skin test results must be interpreted in light of their previous BCG vaccination.

The two-step testing procedure does not identify those persons who are truly anergic and, therefore, are not capable of mounting a typical immune response to the test material. Evaluation of adequate immune response, when determined to be necessary by the physician or other licensed health care professional, as appropriate, is determined through anergy testing, and this is provided for in the explanation of TB skin testing in paragraph (g)(2)(iii).

The CDC recommendations are the guiding documents for TB skin test protocols. By referring the employer to these recommendations in Paragraph (g)(1)(iii)(D), OSHA allows for future changes in protocols and procedures that result from continuing research. Consistent with the CDC guidelines (Exs. 3–33, 3–35, 3–32, 6–15), the American Thoracic Society recommends:

> The Mantoux test with 5 Tuberculin Units (TU) of PPD may be used as a diagnostic aid to detect tuberculous infection and to determine the prevalence of infection in groups of people. (Ex. 5–4)

Proper administration of a TB skin test results in a reaction described as a classic example of a delayed (cellular) hypersensitivity reaction. This reaction indicates infection with mycobacterium, most commonly *M. tuberculosis.* The reaction characteristically begins in 5–6 hours, is maximal at 48–72 hours, and subsides over a period of days (Ex. 5–4).

Proper administration and interpretation of the test is critical and can be complex. In 1990, the American Thoracic Society revised the criteria for interpreting the TB skin test (Ex. 5–4). Information such as the health status of the tested employee, history of BCG vaccination, recent close contact with persons with active TB, chest x-ray results, and other factors must be considered when interpreting the TB skin test results. CDC has established criteria for a TB skin test *conversion*; that is, when an employee's TB skin test results change from negative to positive, indicating a recent TB infection (Ex. 4–B).

Because of the complexity in properly administering and interpreting TB skin tests, it is essential that only trained individuals perform this function. For this reason, TB skin testing is to be administered and interpreted by or under the supervision of a physician or other licensed health care professional as appropriate and according to CDC recommendations. This language allows employers to chose from a variety of health care professionals who can administer and interpret TB skin tests. OSHA is aware that in some worksites, employees have been allowed to read and interpret their own skin test results. A surveillance system that allows self-reading and interpretation of TB skin tests can be problematic. With regard to interpretation of TB skin test results, the American Thoracic Society states:

> Intelligent interpretation of skin test results requires a knowledge of the antigen used (tuberculin), the immunologic basis for the reaction to the antigen, the technique(s) of administering and reading the test, and the results of epidemiologic and clinical experience with the test. (Ex. 5–4)

In its 1994 *Core Curriculum on Tuberculosis* (Ex. 7–93), CDC describes the complexities of interpreting the induration resulting from TB skin testing. A number of factors can affect the size of a TB skin test induration relative to whether or not the test should be interpreted as being positive. For example, induration of 5 mm or more is classified as positive for persons with known or suspected HIV infection, while an induration must be 10 mm to be classified as positive in persons who are foreign-born in high prevalence countries. An induration of 15 mm or more is classified as positive in certain other situations. In addition, TB skin

testing can result in both false positive and false negative results.

Clearly, interpreting TB skin test results requires professional expertise and must be performed by or under the supervision of a physician or other licensed health care professional, as appropriate, by an individual with training and experience in performing the test and interpreting the result. Proper use of the TB skin test as a medical surveillance tool will require two visits to the health care professional: one to receive the test and one to read/interpret the test results. However, considering the critical importance of this element, OSHA believes that allowing employees to read and interpret their own tests or allowing their peers to do so (unless they meet the criteria discussed above) compromises the quality and accuracy of the testing procedure.

Paragraph (g)(2)(iv) describes the determination of each employee's ability to wear a respirator and of his or her need for re-fit testing for employees required to wear a respirator. This face-to-face determination includes a verbal exchange between the employee and the examiner regarding the employee's health factors such as illness or injuries, that may impact his or her ability to wear a respirator (e.g. vascular or heart disease, asthma, claustrophobia, facial structure defects, certain skin conditions, etc.) (Ex.7–64). Based on this history and the observation of the employee, the need for further testing or physical examinations for the ability to wear a respirator can be determined. In addition, assessment of the need for re-fit testing is to be performed, which assures that the examiner consider whether re-fit testing is needed. OSHA has included a note stating that the determination of the need for re-fit testing may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, as, for example, when a different size or make of respirator is used.

Paragraph (g)(2)(v) explains that medical management and follow-up include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease. The employer must provide medical management and follow-up for occupationally exposed employees with skin test conversions [paragraph (g)(3)(i)(D)], or those who undergo an exposure incident whether or not they are categorized as occupationally exposed [paragraphs (g)(1)(ii) and (g)(3)(i)(C)]. In addition, any time an occupationally exposed employee develops signs and symptoms of infectious tuberculosis, medical management and follow-up are required [paragraph (g)(3)(i)(B)]. John E. McGowan addressed follow-up in the 1995 article entitled ''Nosocomial Tuberculosis: New Progress in Control and Prevention,'' published in Clinical Infectious Diseases. He states,

> If the PPD skin testing program for health care workers is to be useful, several steps are crucial. * * * The institution also must make sure that the occupational health service undertakes careful follow-up of workers found to have positive TB skin tests or tuberculosis disease. This follow-up should include counseling, careful monitoring of therapy (when prescribed) until its completion and evaluation of fitness to return to work. (Ex. 7–248).

Paragraph (g)(2)(vi) explains that other related tests and procedures are any TB-related tests and procedures determined to be necessary by the physician or other licensed health care professional, as appropriate. These procedures or tests could include chest radiographs, sputum smears, or other testing determined to be necessary to make an assessment, a diagnosis, or medically manage the employee. An example of a program that integrates testing and examinations was given at the 1994 meeting of the Society for Occupational and Environmental Health, by Carol Murdzak who presented the University of Manitoba's Medical Surveillance program. Her presentation, entitled ''Conducting a Medical Surveillance Program to Prevent and Control Transmission of TB in a Health Care Institution'' demonstrates the use of skin testing and general review of health status for employee surveillance. Results of TB skin testing and the review of health status determine the need for chest x-ray and further medical evaluation in this program (Ex.7–169).

(3) Application

Medical examinations in the form of medical histories, physical examinations, TB skin testing and other related tests and procedures are necessary in order to promptly identify and treat employees with infectious tuberculosis.

Paragraph (g)(3), Application, specifies what an employer must provide. In each situation set forth in paragraph (g)(3), the employer must provide medical examinations, tests and procedures as specified. Some of the provisions are offered only ''if indicated,'' which means that the physician or other licensed health care professional, as appropriate, has determined that further tests or procedures are needed. For example, an employee who has no history of illness or being immunocompromised and whose TB skin test is negative at the time of initial assignment is not required to be offered a physical examination unless the examiner determines that a physical examination is indicated. However, if at the time of annual skin test, the employee has a skin test conversion, a physical examination is required.

Paragraph (g)(3)(i)(A) requires that, before the time an employee is initially assigned to a job with occupational exposure (or within 60 days from the effective date of the standard for employees already assigned to jobs with occupational exposure), the employee be provided with a medical history, TB skin testing, and, if indicated, a physical examination and other related tests and procedures.

OSHA requires the initial medical history to assist in assessing the employee's health. This information will provide a baseline health status that can be used to evaluate (1) whether the employee has a pre-existing condition that may be exacerbated by occupational exposure to TB and (2) any future health conditions that may arise that are relevant to occupational exposure to TB.

OSHA does not believe that an initial physical examination for all occupationally exposed employees is necessarily warranted. However, the Agency does believe that a physical examination, if determined to be indicated by the examiner based on the medical history and TB skin test results, is useful and effective.

The note to paragraph (g)(3)(i)(A) specifies that if an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has documentation of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The Agency realizes that employees may have received at least some of the elements of the required medical surveillance provisions shortly before the effective date of the standard. In these situations, a full TB examination would not need to be repeated.

In addition, the proposed standard allows the baseline TB skin testing status of an employee to be established by documentation of a TB skin test that was administered within the previous 12 months. For example, if an employee has a written record of a TB skin test within the last 12 months, that information can be used to document the employee's baseline TB skin test status and another TB skin test at the

time of the initial medical examination is not necessary. When utilizing results from a previous medical examination and skin test to fulfill the initial medical surveillance requirements, the employer must use the date(s) of the previous medical exam and skin test to determine the date(s) of the employee's next medical examination and skin test. In no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months. These provisions are designed to avoid unnecessary testing of employees and do not compromise the quality of the medical surveillance.

Information (e.g., medical history) obtained from a medical examination in the past 12 months is unlikely to change within this span of time. However, this may not be the case with regard to previous skin testing results. While OSHA is proposing to accept a skin test performed within the past 12 months as a substitute for performing an initial baseline skin test, an employer utilizing a new employee's negative skin testing result obtained more than 3 months prior to beginning the new job may be uncertain as to the source and time of infection if the employee tests positive at his or her next skin test. More specifically, conversion normally occurs within 3 months of infection. Therefore, an employee would have been negative at his or her last skin test, e.g., 7 months previously, and have been infected just after the skin test and subsequently converted. In such a case, an employer may rely on the previous negative skin test as the baseline does not need to test the new employee until 5 months later (i.e., annual skin test frequency), at which time the employee would test positive and be identified as a converter. In this situation, the new employer would not be able to determine if the employee's conversion had occurred as a result of exposure occurring previous to hire or from exposure in his or her current work setting. Regardless of the source of the conversions, the employer would be required by the standard to initiate medical management and a follow-up investigation, which might also entail skin testing other employees in the worksite to determine if other conversions had taken place, a step that would not be necessary if the employee had been correctly identified as positive upon entry into the workplace. In view of this, employers may choose to perform an initial baseline skin test on each new employee before the employee enters the work setting.

Once an employee is on the job, paragraph (g)(3)(i)(A) requires employers to periodically retest employees who have negative TB skin tests in order to identify those employees whose skin test status changes, indicating that they have been infected. Because the baseline TB skin test provides only a ''snapshot'' of the TB skin test status of the employee and because exposure and subsequent infection can occur at any time, periodic testing is necessary. The American Thoracic Society recommends:

> * * * follow-up skin-testing should be conducted on at least an annual basis among the staffs of TB clinics, health care facilities caring for patients with HIV infection, mycobacteriology laboratories, shelters for the homeless, nursing homes, substance-abuse treatment centers, dialysis units, and correctional institutions. (Ex. 5–80)

When TB exposure results in infection, early identification allows employees to have options regarding prophylactic treatment, thereby reducing the likelihood that the infection will progress to disease.

OSHA recognizes the importance of periodic testing to monitor the status of employee's skin test results. In their 1994 Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, the CDC recommends that the frequency of PPD skin testing of employees be based upon the individual facility's risk assessment in conjunction with the criteria put forth by the CDC (Ex. 4B). For situations that meet certain CDC criteria, CDC recommends that employees receive a repeat TB skin test every 3 months, six months or annually, depending upon the risk assessment.

OSHA's proposed standard does not require a risk assessment of the type described by CDC and would extend coverage to worksites other than ''health-care facilities'' as described in the CDC document (Ex. 4B). Consequently, OSHA is proposing that repeat TB skin test be performed every 6 months or annually, depending upon the exposure determination. This testing frequency is expected to be both practical and effective in early identification of skin test conversions in the various worksites described in the Scope. The requirements for more frequent TB skin tests (e.g., 3 months after an exposure incident, or if deemed necessary by a licensed health care professional) ensures that employees' health is not compromised.

An exemption to this annual testing is permitted for an employer who can demonstrate 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 had no cases of confirmed infectious TB in the past 12 months, and (3) is located in a county that, in the past two years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. In these settings only a baseline TB skin test is required. This is discussed earlier under paragraph *b, application*.

Paragraph (g)(3)(i)(B) requires that, when an employee has signs or symptoms of TB, either observed or self-reported, the employee be provided a medical history, physical examination, TB skin testing, medical management and follow-up, and other related tests and procedures determined to be necessary. CDC states that the presence of signs or symptoms of tuberculosis in the employee requires prompt medical evaluation (Ex. 7–52, 7–93), and such evaluation provides an opportunity for initiating drug therapy. Furthermore, identifying those with infectious pulmonary TB disease enables the employer to remove them from the workplace, preventing exposure of other employees.

Paragraph (g)(3)(i)(C) requires that when an employee incurs an exposure incident, a medical history, TB skin testing, medical management and follow-up, and, if indicated, a physical examination and other related tests and procedures be provided. Evaluation and follow-up after each exposure incident help detect any resultant infections, as well as prevent infection in other employees, benefitting the health of all employees.

Following exposure, infected workers will usually develop a positive response to a TB skin test (Exs. 7–50, 7–93, 5–4). In certain cases, workers may also display signs or symptoms compatible with tuberculosis disease such as complaints of persistent cough (over 3 weeks in duration), bloody sputum, night sweats, weight loss, loss of appetite or fever. Use of the TB skin test has been recognized as a tool in the early identification of infection and for disease surveillance and follow-up. In paragraph (g)(3)(i)(C), the proposed standard also requires employers to provide testing for employees as soon as feasible after an exposure incident, unless a negative TB skin test has been documented within the preceding 3 months. If this baseline skin test is negative, another TB skin test shall be repeated 3 months after the exposure incident.

In order to accurately determine if an exposure incident has resulted in infection, the employer must first know the baseline skin test status of the affected employee(s) at the time of the exposure incident. Typically, skin test conversion can be documented approximately 2–10 weeks following

infection (Ex. 7–52). Consequently, it can be reasonably assumed that a negative TB skin test within the three months prior to the incident is sufficiently indicative of the employee's status at the time of the exposure incident.

For those employees who do not have a documented negative skin test within the past three months, the employer must determine their TB skin test status as soon as feasible after the exposure incident. The requirement of ''as soon as feasible'' in the provision puts the employer under the obligation of performing the TB skin test quickly, i.e., before infection resulting from the exposure would be manifested as a conversion. This assures that a true indication of the employee's skin test status at the time of the incident is obtained.

The purpose of the initial TB skin test following an exposure incident is to establish the TB skin test status of the employee(s) at the time of the incident. From this baseline, changes in TB skin test status can be identified. This initial test would not detect infection resulting from the exposure, since there would not have been sufficient time for conversion to occur. Hence, the employer is required to provide a repeat TB skin test three months after the exposure incident to determine if infection has occurred. This requirement reflects current CDC recommendations (Ex. 4B).

Paragraph (g)(3)(i)(D) requires that when an employee has a TB skin test conversion, the employee receive a medical history, a physical examination, medical management and follow-up, and other tests and procedures determined to be necessary. This provision assures that employees with skin test conversions receive appropriate evaluation for preventive therapy and for infectious tuberculosis. OSHA included the provision for early identification of disease since, as the CDC has stated in their guidelines, infectious tuberculosis disease can be prevented by the early treatment of tuberculosis infection.

In paragraph (g)(3)(i)(E), the proposed standard requires employers to provide TB skin testing within 30 days prior to termination of employment. The rationale for this requirement is two-fold. First, this requirement permits employees whose employment is terminated after an unrecognized exposure incident, but before their next regularly scheduled TB skin test, to determine their current (exit) TB skin test status. OSHA recognizes that in some instances employees may be in the process of converting from negative to positive TB skin test results at the time of the exit testing and that some of these cases will be missed. Also missed will be employees who decline testing or who vacate their position immediately or without notice. While such situations are possible, the Agency believes that these occurrences would be rare. Secondly, by detecting recent conversions, appropriate steps can be taken by the employer to investigate the cause of the exposure. This helps prevent future exposures in those areas or situations where the exiting employee's infection may have occurred.

Paragraph (g)(3)(i)(F) requires that a medical history, physical examination, TB skin testing, determinations of the employee's ability to wear a respirator, medical management and follow-up or other related tests and procedures be conducted at any other time determined necessary by the physician or other licensed health care professional, as appropriate. This allows the physician or other licensed health care professional, as appropriate, to recognize the individual differences in employees' medical status and response to TB infection and increase the frequency or content of examination as needed. Some workers who have certain health conditions may need more frequent evaluation (Ex. 4B). For example, individuals who have a condition that may interfere with an accurate interpretation of TB skin test results (e.g., the development of test anergy in an employee who is on chemotherapy for cancer treatment), may warrant more frequent evaluations because of the high risk for rapid progression to TB disease if he or she becomes infected. (Ex. 4B)

Paragraph (g)(3)(ii) sets forth provisions regarding employees who wear respirators. Paragraph (g)(3)(ii)(A) requires that a face-to-face determination of the employee's ability to wear the respirator be accomplished before initial assignment to a job with occupational exposure (or within 60 days of the effective date of the standard) and at least annually thereafter. As discussed above under explanation of terms, this is a verbal exchange to assess health factors that could affect the employee's ability to wear a respirator. An initial determination is made before assignment to a job requiring respirator use to assure that the employee's health factors have been properly evaluated prior to incurring exposure to *M. tuberculosis.* This determination must also be made annually to assure that no health conditions have arisen that might limit an employee's ability to wear a respirator.

Such conditions may arise and be noted prior to the annual determination. For example, the employee may experience unusual difficulty while being fitted or while using the respirator. In these situations, it is not appropriate to wait until the annual determination. Therefore, paragraph (g)(3)(ii)(B) requires that a face-to-face determination of the employee's ability to wear a respirator, including relevant components of a medical history and, if indicated, a physical examination and other related tests and procedures, be provided whenever the employee experiences unusual difficulty while being fitted or while using a respirator.

Paragraph (g)(3)(iii) requires employers to provide TB skin tests every 6 months for each employee who enters AFB isolation rooms or areas, performs or is present during the performance of high-hazard procedures, transports or is present during the transport of an individual with suspected or confirmed infectious TB in enclosed vehicles, or works in intake areas where early identification is performed in facilities where 6 or more individuals with confirmed infectious TB have been encountered within the past 12 months. OSHA believes that employees who perform these activities are exposed more intensely and frequently to individuals with suspected or confirmed infectious tuberculosis and should, therefore, be tested more frequently.

(4) Additional Requirements

Paragraph (g)(4) (i) through (iv) contain the additional requirements an employer must meet. Paragraph (g)(4)(i) requires that the physician or other licensed health care professional, as appropriate, verbally notifies the employer and the employee as soon as feasible if an employee is determined to have suspected or confirmed infectious tuberculosis. In this way an infectious employee can be removed from the workplace, thereby minimizing occupational exposure for other workers. Paragraph (g)(7)(i), Written Opinion, allows 15 days before the employer must provide the employee with the written opinion of medical evaluations from the physician or other licensed health care professional, as appropriate. In situations where an employee is determined to be potentially infectious, this time period leads to unnecessary delays in removal from the workplace and disease treatment. Therefore, OSHA requires the verbal notification to expedite treatment

and prevent spread of disease to other employees.

The proposed standard, in paragraph (g)(4)(ii), requires the employer to notify each employee who has had an exposure incident when the employer identifies an individual with confirmed infectious TB who was previously unidentified. For example, if a newly admitted patient undergoes diagnostic and therapeutic evaluation for suspected pulmonary malignancy, and the diagnosis of infectious tuberculosis is not made until several days after hospitalization, all hospital staff who have had exposure must be identified and provided TB skin test and follow-up. OSHA intends to assure that employees are provided with opportunities for early detection of tuberculosis infection. These provisions are consistent with the general purpose of tuberculosis medical surveillance as recommended by the CDC, and they are included to assist all employees in receiving the full benefits provided by the standard.

Determination of the drug susceptibility of the *M. tuberculosis* isolate from the source of an exposure incident resulting in a TB skin test conversion is required by paragraph (g)(4)(iii) unless the employer can establish that such a determination is infeasible. Information regarding drug susceptibility assists the examiner in deciding the most effective treatment therapy for the exposed employee, particularly if the source is a drug resistant strain of *M. tuberculosis.* Drug susceptibility testing of the source isolate is recommended by CDC (Ex. 4B). OSHA includes the provision regarding infeasibility because certain TB skin test conversions may involve unknown exposure sources. This can make identification of the isolate and therefore drug susceptibility testing infeasible or even impossible. It is the responsibility of the employer to establish that this is infeasible, if such is the case. Employers must make a good faith effort to identify *M. tuberculosis* isolates and obtain the drug susceptibility testing.

Paragraph (g)(4)(iv) requires the employer to investigate and document the circumstances surrounding an exposure incident or TB skin test conversion and to determine if changes can be instituted that will prevent similar occurrences in the future.

The provision assures that employers obtain feedback regarding the circumstances of employee exposures and use the information to eliminate or decrease specific circumstances leading to exposure. For example, exposure incident investigation shows that an employee was exposed to tuberculosis as a result of recirculation of air containing infectious droplet nuclei. Further investigation shows inadequate local or general ventilation in the workplace. The employer can now repair the ventilation system and prevent future exposure incidents. Another example of corrective measures may be including a stronger training emphasis on certain procedures where proper work practices might have decreased the likelihood of transmission of tuberculosis. Employers can obtain further guidance regarding investigations for TB skin test conversions and exposure incidents in health care workers by reading the 1994 CDC guidelines.

(5) Medical Removal Protection

Paragraph (g)(5)(i) requires that employees with suspected or confirmed infectious tuberculosis be removed from the workplace until determined to be non-infectious according to current CDC recommendations. Infectious TB is contagious and removal is essential for the protection of other workers. An employee's ''infectiousness'' is determined by the physician or other licensed health care professional, as appropriate, who informs the employer as required in paragraphs (g)(4)(i) and (g)(7) of this section.

Paragraph (g)(5)(ii) states that for employees removed from the workplace under paragraph (g)(5)(i), the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the right to former job status, as if the employee had not been removed from the job or otherwise been medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first. Paragraph (g)(5)(iii) provides medical removal protection for employees removed from the workplace under paragraph (f)(4)(viii) of Respiratory Protection. The provision requires the employer 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. OSHA requires that if no such work is 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 18 months, whichever comes first.

The requirement referring to the employee's right to return to his or her former job is not intended to expand upon or restrict any rights an employee has or would have had, to a specific job classification or position under the terms of a collective bargaining agreement. Where the employer removes an employee from exposure to tuberculosis, the employee is entitled to full medical removal protection benefits as provided for under the standard.

The medical removal requirement is an indispensable part of this standard. The medical removal protection helps assure that affected employees participate in medical surveillance and seek appropriate care. If employees fear losing their jobs as a result of their medical condition they may attempt to hide the illness, thereby infecting many more workers and other people and jeopardizing their own health. The requirement for medical removal assures that an infectious employee will not be terminated, laid off, or transferred to another job (possibly at a lower pay grade) upon returning to work. Consequently, this protection should reduce reluctance on the part of the employee to participate in medical surveillance. The employee's health will be protected and the health of co-workers and others who come into contact with that employee will be protected, also.

OSHA believes that the cost of protecting worker health to the extent feasible is an appropriate cost of doing business since employers are obligated by the OSH Act to provide safe and healthful places of employment. Consequently, the costs of medical removal, like the costs of respirators and engineering controls, are borne by employers rather than individual workers.

If a removed employee files a claim for workers' compensation payments for a tuberculosis-related disability, then the employer must continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation may be reduced by such amount. The employer's obligation to provide medical removal protection benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer which was made possible by virtue of the employee's removal.

Medical removal should not be viewed as an alternative to primary control (prevention) of workers' exposure to tuberculosis; rather, it should be used as a secondary means of

protection, where other methods of control have failed to protect. The stipulation of an 18 month time period of protection is consistent with other OSHA standards (e.g., Cadmium, 29 CFR 1910.1027; Lead in Construction, 29 CFR 1926.62). The provision of medical removal and the costs associated with the program may indirectly provide employers with economic incentives to comply with other provisions of the standard. It can be expected that the costs of medical removal will decrease as employer compliance with other provisions of the standard increases.

(6) Information Provided to Physician or Other Licensed Health Care Professionals

Paragraph (g)(6)(i) requires the employer to assure that the health care professionals responsible for the medical surveillance receive a copy of this regulation. OSHA believes it is the employer's responsibility to inform the health care professionals responsible for medical surveillance of the requirements of this standard. This will help assure that these individuals are aware of and implement the requirements. This provision is included in other OSHA standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(6)(ii) requires the employer to assure that the physician or other licensed health care professional, as appropriate, evaluating an employee after an exposure incident receives: (A) A description of the exposed employee's duties as they related to the exposure incident; (B) a description of the circumstances under which the exposure incident occurred; (C) the employee's diagnostic test results, including drug susceptibility pattern, or other information relating to the source of exposure that could assist in the medical management of the employee; and (D) all of the employee's medical records relevant to the medical evaluation of the employee, including TB skin test results. Since the individual responsible for medical surveillance may not necessarily be the person evaluating an employee after an exposure incident, it is necessary to also provide a copy of this standard to the evaluating physician or other appropriate licensed health care professional, as required by paragraph (g)(6)(i). In this way, the evaluator will also be informed of and implement the standard's requirements. All of the above information is essential to follow-up evaluation, and helps assure that an accurate determination can be made regarding appropriate medical treatment of the exposed employee. This provision is consistent with other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030, Benzene, 29 CFR 1910.1028).

(7) Written Opinion

Paragraph (g)(7)(i) states that the employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section. The purpose of requiring the employer to obtain a written opinion is to assure that the employer is provided with documentation that the medical evaluation of the employee (1) has taken place and that the employee has been informed of the results; (2) has included an evaluation of the employee's need for medical removal or work restriction; (3) describes the employee's TB skin test status so that the employer can assess action needed to prevent further exposure; and (4) informs the employer of the employee's infectivity status so that the employer can take action to prevent the employee from becoming a source of infection for other employees.

The employer has a right to know the information contained in the written opinion and may retain the original written opinion, but must provide a copy to the employee. The 15 day provision assures that the employee is informed in a timely manner regarding information received by the employer and is consistent with other OSHA standards (e.g., Formaldehyde, 29 CFR 1910.1048; Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

In addition, the written opinion is required to assure the employer that the employee has been provided with information about any medical conditions resulting from exposure to tuberculosis which require further evaluation or treatment.

OSHA believes it is important that employers know if their employees have had evaluations for tuberculosis infection or exposure incidents, and that physicians or other appropriate licensed health care professionals, acting as agents for the employer, have provided the employer with written documentation that these evaluations occurred. However, paragraph (g)(7)(ii) limits the information the employer is provided in order to protect the privacy of the employee. The requirement for a written opinion after a medical evaluation has been included in other OSHA standards (e.g., Occupational Exposures to Hazardous Chemicals in Laboratories, 29 CFR 1910.1450; Formaldehyde, 29 CFR 1910.1048; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(7)(ii)(E) requires the written opinion to state any recommendations for medical removal or work restrictions and the employee's ability to wear a respirator. This recommendation must be in accordance with paragraphs (g)(5)(i) and (f)(5)(viii) of this section. Including this information in the written opinion assures that the employer is provided with written documentation of the need for removal of an employee with infectious tuberculosis from the workplace. The provision also assures that the employer is aware of any work restrictions on the employee and the employee's ability or inability to wear a respirator. This information enables the employer to take appropriate steps in managing the employee's duties upon return to the workplace. OSHA recognizes the need for this provision and has included it in other standards (e.g., Lead in Construction, 29 CFR 1926.62).

Paragraph (g)(7)(iii) states that all other findings or diagnoses shall remain confidential and shall not be included in the written report. OSHA believes that all health care professionals have an obligation to view medical information gathered or learned during tuberculosis medical surveillance or post-exposure evaluation as confidential medical information. As stated previously, the maintenance of confidentiality encourages participation in medical surveillance by allaying employee concern that medical conditions unrelated to tuberculosis exposure will be communicated to the employer. OSHA also recognizes that successful medical surveillance and medical management and follow-up programs must guarantee this confidentiality, the specific requirements on confidentiality can be found in applicable state and federal laws and regulations that cover medical privacy and confidentiality. Finally, OSHA recognizes the need for this provision and has included it in other standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (h) Communication of Hazards and Training

Paragraph (h), Communication of Hazards and Training, addresses the issues of transmitting information to employees about the hazards of tuberculosis through the use of labels, signs, and information and training. These provisions apply to all operations that come under the coverage of

paragraph (*a*), *Scope*, of this section. Although OSHA has an existing standard, Hazard Communication (29 CFR 1910.1200), which requires an employer to inform employees about the hazards of chemical substances they are exposed to occupationally, that standard does not apply to biological hazards such as TB. Consequently, it is OSHA's intent in this paragraph to assure that employees will receive adequate warning through labels, signs, and training so that the employee understands the hazard and can take steps to eliminate or minimize his or her exposure to tuberculosis.

Paragraphs (h)(1) and (h)(2) of the proposed standard for tuberculosis provide the specific labeling and sign requirements that are to be used to warn employees of hazards to which they are exposed. The requirements for labels and signs are consistent with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of occupational hazards. As noted in paragraphs (c)(2)(v), (d)(3), and (d)(5) above, settings where home health care and home-based hospice care are provided are not required to have engineering controls and, therefore, the signs and labeling would not be required in these cases.

Labels

Paragraph (h)(1)(i) requires that air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* must be labeled at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and discharge outlets of non-HEPA filtered direct discharge systems. The label must state ''Contaminated Air—Respiratory Protection Required.'' The provision for labeling of air ducts that may reasonably be anticipated to contain aerosolized *M. tuberculosis*, with the proposed hazard warning, is supported by the CDC in its discussion of HEPA filter systems. This discussion states:

> Appropriate respiratory protection should be worn while performing maintenance and testing procedures. In addition, filter housing and ducts leading to the housing should be labeled clearly with the words ''Contaminated Air'' (or a similar warning). (Ex. 4B)

The intent of this provision is to assure that employees who may be accessing these systems for the purposes of activities such as maintenance, replacement of filters, and connection of additional ductwork are warned of the presence of air that may contain aerosolized *M. tuberculosis* so that appropriate precautions can be taken. Consequently, labels are to be placed at all points where these systems are accessed.

In situations where air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is discharged directly to the outside, the exhaust outlets are also to be labeled. This is especially important since these outlets will most likely be at a remote location from the contaminated air source. Employees working in these locations would have no warning of the hazard if these ducts were not labeled. In addition, a number of exhaust outlets from a variety of sources may be present in an area (e.g., a hospital roof). In such situations, labeling also serves to distinguish contaminated air exhaust outlets from others in the vicinity.

The proposed provision does not require that a symbol (e.g., ''STOP'' sign) be included on the duct labels. OSHA believes that, in many situations, the label will be stenciled onto the duct, similar to the labeling used on other piping and duct labels currently being employed in some of these facilities. In addition, the group of workers accessing ducts will likely be a well-defined, skilled group that can be trained to recognize the text's warning. However, OSHA seeks comment on whether a symbol on duct labels is necessary and any information regarding the current use of such symbols.

Paragraph (h)(1)(ii) requires that clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory must be labeled with the biohazard symbol or placed in a red container(s). This provision is intended to assure that employees are adequately warned that these containers require special handling. In addition, the label or color-coding serves as notice that certain precautions may be necessary should materials in the container be released (e.g., a spill). This provision closely follows the recommendations outlined in the CDC-NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72) and is in accordance with the labeling requirements of paragraph (e)(2)(i)(D), Clinical and Research Laboratories, of this section.

Signs

Paragraph (h)(2) contains the provisions relative to the posting of warning signs in areas where employees may be exposed to droplet nuclei or other aerosols of *M. tuberculosis*. More specifically, paragraph (h)(2)(i)(A) requires that signs be posted at the entrances to rooms or areas used to isolate an individual with suspected or confirmed infectious TB. The term ''rooms or areas'' is used in order to expand the requirement beyond the AFB isolation room or area. Throughout the course of a day various employees may enter such rooms or areas in order to carry out their duties. These employees can include physicians, nurses, respiratory therapists, housekeepers, and dietary workers. Posting a sign at the entrance of those rooms or areas where an individual with suspected or confirmed infectious TB is isolated serves to warn employees that entry into the room or area requires that certain precautions be taken. In addition, the employer may have implemented a program to minimize the number of employees who enter such rooms or areas. In this case, the sign serves as notice that entry may not be permitted for a particular employee or group of employees. As an additional public health benefit, such signs will also provide warning to visitors or family members who may be entering the area and are unaware of the hazard.

Paragraph (h)(2)(i)(B) requires that signs be posted at the entrances to areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB. Although it is critically important to provide appropriate warning to employees who may inadvertently enter an isolation room, other areas of the facility are of concern as well. Special treatment areas, such as bronchoscopy suites, respiratory therapy areas where cough-inducing procedures are performed, or radiology examination rooms may, at one time or another, be occupied by an individual with suspected or confirmed infectious TB. When individuals with suspected or confirmed tuberculosis are occupying these areas, the area must have signs placed at the entrances in order to warn employees of the hazard.

The risk of exposure to aerosolized *M. tuberculosis* also exists in clinical and research laboratories where specimens, cultures, and stocks containing the bacilli are present. Therefore, paragraph (h)(2)(i)(C) requires that a sign be posted at the entrance to laboratories where *M. tuberculosis* is present. Posting of such a sign is consistent with the recommendations of the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72) and is in accordance with the sign posting requirement of paragraph (e)(2)(ii)(E), Clinical and Research Laboratories, of this section.

Even though a suspected or confirmed infectious individual is no longer present in a room or area, the droplet nuclei generated by that individual may continue to drift in the air. Consequently, the air in the room or area presents a risk of TB infection until the droplet nuclei are removed. With this in mind, paragraph (h)(2)(ii) requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9%, to prevent entry without the use of respiratory protection [The rationale for specifying this removal efficiency has been discussed previously under paragraph *(d), Work Practices and Engineering Controls*]. This provision is supported by the CDC's current recommendations for tuberculosis control (Ex. 4B).

The CDC has published guidelines regarding the length of time for such sanitation of the room air based upon the air exchanges per hour (see Appendix C of this section). Requiring that the sign remain posted until the room or area is adequately ventilated will assure that unprotected employees do not inadvertently enter while an infection risk is still present.

Until such time as the room or area has been adequately ventilated, employees entering the area must wear respiratory protection. This paragraph is designed to address the situations where employees will be entering or using a room or area previously occupied by an individual with suspected or confirmed infectious TB before the room or area has been satisfactorily ventilated. For example, when an infectious tuberculosis patient is discharged from a facility and the room is needed for an incoming new patient, certain housekeeping and maintenance functions need to be done between patient occupancies. Employees who must perform the tasks required to prepare the room for the next patient must wear respiratory protection until such time as the room has been adequately ventilated, based upon the CDC criteria. Obviously, if the room was previously occupied by an individual with suspected infectious TB and that individual is medically determined to be noninfectious, it would not be necessary to ventilate the room to remove *M. tuberculosis* nor to continue to post a sign at the entrance to the room since there would be no tuberculosis bacilli present.

OSHA has given much consideration to what sign should be required for posting outside of isolation rooms or areas and for areas where procedures or services are performed on individuals with suspected or confirmed infectious TB. The purpose of the sign is to convey a uniform warning along with the necessary precautions to be used for the particular situation.

The sign recommended by the CDC in 1983 in their ''CDC Guidelines for Isolation Precautions in Hospitals'' (Ex. 7–112) read ''AFB Isolation'' and then listed the requirements for entry. However, the instructions on the CDC sign are different from OSHA's requirements. For example, the sign instructed workers that ''Masks are indicated only when patient is coughing and does not reliably cover mouth'', a recommendation that is currently outdated and no longer recommended by CDC. The document contained another sign for ''Respiratory Isolation'' but this sign was designed for use with a number of respiratory hazards (rubella, meningococcal meningitis, chickenpox) that are not addressed in OSHA's proposed standard. Neither the 1990 CDC tuberculosis guidelines (Ex. 3–32) nor the 1994 CDC tuberculosis guidelines (Ex. 4B) provided help with this issue. OSHA also considered using a sign having the words ''AFB Isolation'' however, there is some concern that ''AFB Isolation'' could compromise patient confidentiality. For example, that sign outside of a treatment area or isolation room would allow members of the public or employees with no ''need to know'' to discern the potential diagnosis of the individual being isolated.

In addition, OSHA was unable to find uniform recommendations about signs in sources outside of the CDC. A number of facilities use signs to warn employees of the hazard of TB, but these signs vary widely and often had been developed for a particular facility. Thus, facilities that were using TB warning signs did not appear to be universally applying a specific sign.

The Agency does not believe, however, that development of a sign should be left to individual employers since this could lead to a variety of signs that may not provide adequate warning of the hazard. In the work settings covered by the proposal, there are many employees who move from facility to facility or even from industry to industry. In fact, a substantial number, like contract nurses, will work in several facilities at one time. A universal sign will enable these employees to recognize the hazard wherever it occurs and then take proper precautions. The issue of whether OSHA should specify colors that must be included on the sign was raised at TB stakeholder meetings. OSHA realizes there is a part of the population, perhaps as high as 10% of all men, that is color blind and that at some work sites some colors have been employed that are different from the red that OSHA proposes be used. However, stakeholders, particularly those whose jobs took them to several different work sites, urged OSHA to require a standardized sign and, of those who considered the issue, there was general agreement that the red on the familiar ''stop'' sign was appropriate. OSHA has preliminarily concluded that the colors required provide needed warning even though not all employees (e.g., those who are color blind) may benefit from them, and that the colors chosen are consistent with conventions on health signage. The Agency has developed a sign that it believes will provide appropriate warning and be easily recognizable. Failing to find either a guideline recommendation or a generally accepted community standard regarding what sign should be placed at the entrances to these areas, OSHA looked to generic, broad-based sources for symbols which would be easily identifiable, understandable to workers who were not able to read well or are non-English speaking, and simple to construct.

In paragraph (h)(2)(iii), therefore, OSHA is proposing that a ''STOP'' sign with the accompanying legend, ''No Admittance Without Wearing A Type N95 Or More Protective Respirator'', meets these criteria. The sign is easily recognizable, requires a simple color scheme, and should be understandable to employees with minimal training.

OSHA is seeking information on the effectiveness of the proposed sign to warn workers of the presence of a hazard, as well as information on other signs that may be more effective. Please be specific when providing information, keeping in mind the wide variety of work sites where signs will be needed. Where an alternative is being proposed, please enclose a model or drawing as well as the rationale for believing that it will be more effective than OSHA's proposed sign.

Paragraph (h)(2)(iv) requires that signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation

''*Mycobacterium tuberculosis*'', and special requirements for entering the laboratory or autopsy suite. This provision has been taken directly from the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). As previously discussed, the purpose for this sign is to warn employees of the potential TB hazard and inform them of precautions that must be taken to prevent exposure.

Information and Training

It is OSHA's position that employees must understand the nature of the hazards in their workplace and the procedures to follow in order to eliminate or minimize their risks of exposure to these hazards. (Exs. 4–B, 7–169, 7–170, 7–61, 7–64) In the case of *M. tuberculosis*, employee exposures may result in a TB infection, which may ultimately result in disease and even death. The provisions in paragraph (h)(3) of this proposed standard set forth the training that each employer must provide to his or her employees. OSHA believes that effective training is a critical element in any occupational safety and health program. In this proposed standard, the employer would be required to provide training for each employee covered by the scope of the standard.

Paragraph (h)(3)(i) requires that employers assure that each employee with occupational exposure participates in training, which must be provided at no cost to the employee and be made available at a reasonable time and place. Since appropriate training is considered to be critical in assuring employee protection, the employer is responsible for making sure that each employee with occupational exposure participates in the training program. Having the employee pay in some manner for all or part of the training or requiring the employee to attend training at an unreasonable time and place would be a disincentive to participation. If training cannot feasibly be provided during work hours, employees are to be paid for training scheduled outside of normal working hours.

In view of the importance of training, OSHA is proposing that it be provided at several particular points in time. (Exs. 7–169; 4–B) More specifically, paragraph (h)(3)(ii) requires that training be provided: (A) before initial assignment to tasks where occupational exposure may occur, for those employees without previous occupational exposure; (B) within 60 days after the effective date of the final standard, for those employees who have occupational exposure at the time of the standard's promulgation; and (C) at least annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii). The employer must provide re-training to an employee in any of the topic(s) in paragraph (h)(3)(vii) in which that employee cannot demonstrate the necessary knowledge and/or skill. This approach to training frequency assures that employees entering jobs with occupational exposure will be fully trained before exposure occurs. In addition, employees who are already working in jobs with occupational exposure at the time of the standard's promulgation will receive training and must become knowledgeable in all of the required aspects of the standard (e.g., employer's exposure control plan, medical surveillance program, warning signs and labels) within a short period of time.

Annual re-training reinforces the initial training and provides an opportunity to present new information that was not available at the time of initial training. The Agency recognizes that, as a result of training previously provided by the employer, employees may possess some of the knowledge and skills listed in the training topics in paragraph (h)(3)(vii). Consequently, OSHA is proposing that re-training be provided annually unless the employer can demonstrate that the employee has the specific knowledge and skills required by this paragraph. The employer must provide re-training to an employee in any topic(s) in paragraph (h)(3)(vii) in which the employee cannot demonstrate specific knowledge and skills.

An employee with occupational exposure to TB who moves to a job with another employer that also involves occupational exposure to TB would not need to meet all of the initial training requirements. In such instances, the Agency has determined that the employee's prior training in the general topics required by the standard (e.g., the general epidemiology of tuberculosis, the difference between tuberculosis infection and tuberculosis disease) would remain relevant in the new work setting and that the new employer need not re-train in these topics. However, the employee would not possess knowledge of the topics required by the standard that are specific to the new employer's particular work setting (e.g., the new employer's exposure control plan and respiratory protection program and the means by which the employee could access the written plans for review). OSHA is proposing to permit limited ''portability'' of training, as noted in the standard. This note states that training in the general topics listed in paragraph (h)(3)(vii) that has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics listed in paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h) (e.g., at no cost to the employee and at a reasonable time and place).

OSHA is aware that some employers have already established training for their occupationally exposed employees. (Ex. 7–169) In light of this, paragraph (h)(3)(iii) of the proposed standard requires only that limited training be conducted for those employees who already have received training on tuberculosis in the year preceding the effective date of the standard. The additional training would only have to address those provisions of the standard not previously covered in the earlier training.

The requirement for annual training within one year of the employee's previous training, in paragraph (h)(3)(iv), assures that each employee receives training within 12 calendar months of his or her last training. Annual training is not based on a calendar year; that is, training will not be permitted to be provided to an employee in January of one year and in December of the following year, essentially a 23-month span between training sessions. Employers may establish schedules for training around this requirement.

Also, paragraph (h)(3)(v) stipulates that the employer must provide additional training whenever changes in the occupational environment, such as modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure to *M. tuberculosis*. This provision will assure that employees remain apprised of any new exposure hazards and the precautions necessary to protect themselves from exposure. This additional training does not need to entail a complete reiteration of the annual training, but may be limited to addressing the new sources of potential exposure.

The proposed standard requires that training material be used that is appropriate in content and vocabulary to the educational level, literacy and language of employees. Employees must be able to comprehend the information being conveyed in order for it to be useful. Therefore, the employer has the responsibility for assuring that the training is provided in an understandable manner to the audience being addressed. This provision would

assure that employees, regardless of their educational or cultural background, will receive adequate training.

Paragraph (h)(3)(vii) of the proposed standard contains the specific elements that would comprise a minimum training program. (Exs. 4–B; 7–169; 7–64) The provisions for employee training are performance oriented, stating the categories of information to be transmitted to employees and not the specific ways that this is to be accomplished. This assures that important information is communicated to employees about the nature of this occupational hazard while allowing employers the most flexible approach to providing training. OSHA has set forth the objectives to be met and the intent of training. The specifics of how the employer assures that employees are made aware of the hazards in their workplace and how they can help to protect themselves are left up to the employer who is best qualified to tailor the training to the TB hazards in his or her workplace.

The proposed standard would require the employer to explain a number of particular topics in the training session(s). Paragraph (h)(3)(vii)(A) requires the employer to provide an explanation of the contents of this standard and the location of an accessible copy of the regulatory text and appendices to this standard. This enables the employee to have access to the standard and to become familiar with its provisions. It is not necessary for the employer to provide each employee with a copy of the standard; it is sufficient for the employer simply to make a copy accessible. For example, a copy of the standard could be posted in a location where it could be readily and easily viewed by employees.

An important element in the training involves an overview of the epidemiology of tuberculosis, the pathogenesis of the disease and an explanation of various aspects of risk to employees. (Ex. 4B) More specifically, paragraph (h)(3)(vii)(B) requires that the training include an explanation of: the general epidemiology of tuberculosis, including multidrug-resistant TB and the potential for exposure in the facility; the signs and symptoms of TB, including the difference between TB infection and TB disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase an employee's risk of developing TB disease if infected.

Since the employer can tailor the training to the needs of his or her employees, the training program will likely be more technical for some audiences and less technical for others. The general goal of this paragraph is to assure that each employee being trained understands what tuberculosis is, how it is spread, and possible risks that may affect the employee.

Employees need to be able to recognize symptoms associated with TB disease. (Ex. 4B) The employee must understand that certain symptoms (e.g., a persistent cough lasting 3 or more weeks, bloody sputum, night sweats, anorexia, weight loss, fever) may be related to TB. In addition, information on non-occupational risk factors that place employees at increased risk of developing tuberculosis disease following an infection permits those individuals at increased risk to make informed decisions about their employment situations.

Paragraph (h)(3)(vii)(C) requires an explanation of the employer's exposure control plan and respiratory protection program. Employees must also be informed about what steps they need to take to review the written plans, if they so desire.

Paragraph (h)(3)(vii)(D) requires the employer to train employees regarding the tasks and other activities that may involve occupational exposure to tuberculosis. Employees must be made aware of those job duties which may expose them to tuberculosis. For example, although certain health care professionals may easily recognize the hazard involved in transporting a person with infectious TB, the staff of a correctional facility may not. On the other hand, some health care professionals may not immediately recognize that their mere presence in a room where an individual with suspected or confirmed infectious TB is being X-rayed presents an exposure risk and necessitates wearing a respirator. All occupationally exposed employees need training that will enable them to recognize those activities that put them at risk of exposure.

Paragraph (h)(3)(vii)(E) of this section requires employers to train employees regarding both the uses and limitations of various control measures, specifically those used at the employees' worksite. Exposed employees must be familiar with the employer's tuberculosis policies and procedures in order for them to be properly implemented. Control of exposure frequently involves using a variety or combination of engineering controls, administrative controls, work practice procedures and personal protective equipment. To assure that employees will be able to identify and implement methods of reducing occupational exposure to tuberculosis, they must understand how these controls are applied in their work sites and the limitations thereof. With this understanding, employees will be more likely to use the appropriate control for the situation at hand and to use it correctly. For example, employees must be able to recognize the labels and signs used to identify rooms or areas where suspected or confirmed infectious individuals are present so that they can take appropriate precautions before entering. Understanding of the limitations of control measures will also enable employees to recognize when inappropriate or inadequate control measures have been taken and increases the likelihood that they will report such situations.

Training must be relevant to the specific site where the employee will be working. Each employee must know, for example, the procedures used in his or her particular facility to identify suspected infectious TB cases, where respiratory protection is kept, and what engineering controls are in place within the facility. This training is particularly important for workers who move between several facilities in the course of their work, for example, ''leased'' personnel, part-time employees, ''moonlighters'', or contractors.

The provision covering the selection, types, proper use, location, removal and handling of respiratory protection, paragraph (h)(3)(vii)(F), is particularly important because many of the employees and employers proposed to be covered by the tuberculosis standard may not be accustomed to the use, selection, and upkeep of respiratory protection. Consequently, training on aspects such as the necessity for respiratory protection, the appropriate type of respiratory protection, where to obtain it, and its proper use, fit, and the general upkeep is necessary to assure the effectiveness of respirator use. (Ex. 7–64)

OSHA believes that employees who have a clear understanding of the medical surveillance program (its purpose, methodology, and the significance of the results of examinations and tests), will be much more likely to participate in that program. Therefore, paragraph (h)(3)(vii)(G) requires that the training include an explanation of the employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program. This increased participation by trained

employees helps the employee to identify changes in his or her personal health status and also aids the employer in assessing the effectiveness of his or her TB control program.

Each employee must understand the actions to be taken if an occupational exposure occurs as well as what is available to them regarding appropriate medical treatment, prophylaxis, and post exposure follow-up in order for the employee to lessen the chance of developing active disease. Therefore, paragraph (h)(3)(vii)(H) would require an explanation of the procedures to follow if an exposure incident occurs, including the method of reporting the incident, an explanation of the medical management and follow-up that the employer is required to provide, and the benefits and risks of drug prophylaxis. In addition, the employee must be provided with an explanation of the procedures to follow if the employee develops signs or symptoms of tuberculosis disease [paragraph (h)(3)(vii)(I)]. In this way, an employee who notes the signs or symptoms of personal disease development will be aware of the appropriate steps to take, thereby speeding initiation of medical evaluation. Quick evaluation protects the employee, co-workers, and the public.

In paragraph (h)(3)(viii), the proposed standard mandates that the person conducting the training must be knowledgeable in the subject matter as it relates to the specific workplace being addressed. OSHA believes that a variety of persons are capable of providing effective training to employees. OSHA has approached this section of the proposed standard in much the same way as the trainer requirements were addressed in the standard for Occupational Exposure to Bloodborne Pathogens. That is, a knowledgeable trainer is one who is able to demonstrate expertise in the area of the occupational hazard of tuberculosis and is familiar with the manner in which the elements of the training program relate to the particular workplace.

A number of resources are available through the Centers for Disease Control and Prevention and professional organizations such as the American Lung Association and the American Thoracic Society that can be used to educate trainers and prepare them for this task. In addition, specialized training courses in the area of tuberculosis control can also assist in educating trainers (Ex. 7–189).

In addition to general knowledge of the subject matter, it is important that the trainer be able to instruct the participants in site-specific features of the Exposure Control Plan that will reduce their risk in the particular facility. This benefits not only employees within the facility but also provides temporary employees with the information needed to protect themselves against exposure while working in the facility. For example, workers who have received general training by their employer (e.g., a personnel staffing agency) will also receive training about the facility where they will actually perform their duties (e.g., a specific hospital).

An important component of an effective learning experience is the opportunity for the learner to interact with the trainer for the purposes of asking questions and obtaining clarification. Paragraph (h)(3)(ix) would require that the employer provide employees with this opportunity as part of the training program. The trainer must be available at the time that the training takes place. OSHA would expect that in most instances, the individual who would provide answers to the employee's question would be physically present when the employee is trained. The Agency does recognize, however, that there may be some instances where this is not possible. In these cases, it would be acceptable for the employee to ask questions by telephone.

An employer would not be expected to train employees in site-specific topics that are not applicable to the employer's work setting. For example, if a facility was not required by the standard to utilize engineering controls, the employer would not be responsible for training his or her employees about the various aspects of engineering controls.

OSHA believes that the information and training requirements incorporated into this proposed standard are needed to inform employees about the hazard of tuberculosis and to provide employees with an understanding of the degree to which they can minimize the health hazard. Training is essential to an effective overall hazard communication program and serves to explain and reinforce the information presented to employees on signs and labels. These forms of information and warning will be meaningful only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposure.

OSHA seeks comment on the proposed content of the training program and requests that model TB training programs be submitted to the docket, particularly those designed for audiences whose participants may have language difficulties or have no health care background, and those that have been judged to be successful in communicating information to employees. It is OSHA's intent, upon publication of the final standard, to include information on training programs in compliance guides to be developed for small entities.

Paragraph (i) Recordkeeping

This proposed standard requires employers to keep records related to TB, including medical surveillance and training records for all employees with occupational exposure and engineering control maintenance and monitoring records. OSHA has made a preliminary determination that, in this context, medical and training records are necessary to assure that employees receive appropriate information on hazards and effective prevention and treatment measures, as well as to aid in the general development of information on the occupational transmission of TB. Specifically, OSHA believes that maintenance of medical records is essential because documentation is necessary to ensure proper evaluation of an employee's infection status and for prompt and proper healthcare management following an exposure incident. OSHA has also preliminarily determined that maintenance and monitoring records for engineering controls are necessary for two reasons: to enable the employer to know that the control methods remain in good working order so as to assure their effectiveness and to aid the Agency in enforcement of the standard.

In paragraph (i)(1), OSHA proposes to require employers to establish and maintain a medical record in accordance with 29 CFR 1910.1020 for each employee with occupational exposure to TB. The record must include: (A) The name, social security number, and job classification of the employee; (B) A copy of all results of examinations, medical testing, including the employee's tuberculin skin test status; and follow-up procedures required by paragraph (g); (C) The employer's copy of the physician's or other licensed health care professional's written opinion as required by paragraph (g)(7); and (D) A copy of the information provided to the physician or other health care professional required by paragraph (g)(6). The information that must be included in the medical record is necessary for the proper evaluation of the employee's infection status and management of occupational exposure incidents. This record will aid OSHA in enforcing the standard and the information therein, when analyzed, will further the development of health

data on the causes and prevention of occupational transmission of TB. Similar provisions for collection and retention of such information have been included in other OSHA health standards including, most recently, Bloodborne Pathogens (29 CFR 1910.1030) and Cadmium (29 CFR 1910.1027).

In paragraph (i)(1)(iii), OSHA is proposing to require that the employee medical records be kept confidential and not be disclosed or reported to anyone without the employee's express written consent except as required by section i or as may be required by law. In nearly every health standard rulemaking, employees have told the Agency that keeping medical records confidential is extremely important to them. Employees stated that, without assurance of confidentiality, they would be reluctant to participate in medical surveillance, a predicament that would be detrimental to their health and could affect health and safety conditions in the workplace. During the Bloodborne Pathogens rulemaking, confidentiality of medical records was a major issue due to the nature of the diseases addressed. Of particular concern was keeping the medical records from being disclosed to the employer. It was explained in the Bloodborne Pathogens standard and is applicable here that such confidentiality can be accomplished by having the records kept by the physician or other licensed health care provider at the expense of the employer. In those cases where the employer is the health care provider, the records can be maintained separately from other employee records so that disclosure can be strictly limited to the physician or other licensed health care professional and his or her staff who are responsible for the medical management of the employee. It was pointed out in the preamble to the Bloodborne Pathogens standard, and bears repeating here, that the confidentiality provisions in the proposed standard are reiterations of existing standards of conduct in the health care professions and that the OSHA requirements do not abridge, enlarge or alter existing ethical or statutory codes (56 FR 64170). This section of the proposal requires that medical records be disclosed to the Assistant Secretary or the Director (of NIOSH) and as may be required by law, which means that this proposed standard would not prevent employers from reporting TB cases to federal, state, or municipal health departments where that reporting is required by law.

Paragraph (i)(1)(iv) proposes to require that medical records be maintained in accordance with 29 CFR 1910.1020 for at least the duration of employment plus 30 years. The Access to Medical Records Standard contains an exception to the 30-year requirement that provides that the medical records of an employee who has worked less than one year must be maintained throughout his or her employment, but need not be retained afterwards as long as they are given to the employee upon termination of employment. Maintaining the records for the duration of employment serves several purposes: the records can provide valuable information to the employee's healthcare provider; the records enable the employer to know that employees are benefitting from regular surveillance and timely intervention following occupational exposure to TB; analysis and aggregation of the records can provide insight into the causes and consequences of occupational exposure to TB; and, the records will aid in the enforcement of the standard. Requiring the records to be kept 30 years beyond employment is necessary because TB can have a long incubation period, with disease often appearing only many years after initial infection. This retention time is also consistent with other OSHA health standards (See for example Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030; Ethylene Oxide, 29 CFR 1910.1047).

In paragraph (i)(2), OSHA proposes to require employers to record TB infection and disease in accordance with 29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses, and 29 CFR 1960, the equivalent requirement for Federal Agency programs. This should not be an unfamiliar requirement to employers because occupational TB infections and disease must be reported in accordance with 29 CFR 1904 and 29 CFR 1960, as directed by current OSHA enforcement policy (Ex. 7–1).

In paragraph (i)(3), OSHA proposes to require training records, which include: (A) The dates of the training sessions; (B) The contents or a summary of the training sessions; (C) The names and qualifications of persons conducting the training; and (D) The name and job classification of all persons attending the training sessions. This requirement is consistent with other OSHA standards, particularly Bloodborne Pathogens, and it represents the minimum amount of information an employer, an employee, or an OSHA compliance officer would need in order to determine when and what training had been provided, who administered it and who attended. Additionally, such a record is an invaluable aid to the employer when evaluating his or her training program.

OSHA proposes, in paragraph (i)(3)(ii) to require that training records be maintained for three years beyond the date the training occurred. The Agency anticipates that employers will not have difficulty maintaining the records for three years because the information to be included is not extensive and many employers are already keeping training records three years as required by other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030). Moreover, these records are not required to be kept confidential and so may become part of an employee's personnel file or part of a larger file, at the discretion of the employer.

In paragraph (i)(4), OSHA proposes to require engineering control maintenance and monitoring records be kept that include: (A) Date; (B) Equipment identification; (C) Task performed; and (D) Sign-off. The performance monitoring records must include: (A) Date and time; (B) Location; (C) Parameter measured; (D) Results of Monitoring; and (E) Sign-off. Only two of these items will require more than a few words or numbers to record; the two items that require more extensive information are the maintenance task performed and the results of the performance monitoring. Where the employer has not already developed a method for recording the task performed, the maintenance person can list the tasks or use a previously prepared check-list. The results of performance monitoring can be recorded in the same way or another way that meets the needs of the particular workplace so long as it includes all of the information required by the paragraph. OSHA believes that the information in these records is the usual data that are generated by persons maintaining and servicing equipment so that the status of the equipment and its effectiveness can be known for a given time. The information is also useful in determining when further servicing is needed.

Proposed paragraph (i)(4)(iii) requires engineering control maintenance and monitoring records to be maintained for three years. The three year period is a reasonable period of time and it will enable the employer to develop and sustain a proper maintenance program and to track the effectiveness of the controls. Moreover, the records will aid the OSHA compliance officer in enforcing the standard's requirements for engineering controls.

Availability of medical records is specified in section 8(c) of the Act. In paragraph (i)(5) of this standard, OSHA

proposes to restrict the availability of employee medical records while making employee training records and engineering control and monitoring records generally available upon request. Medical records must be provided to the subject employee, to anyone having written consent from the employee, to the Director and to the Assistant Secretary in accordance with 29 CFR 1910.1020, which sets forth the procedures that will protect the privacy concerns of the employees. This paragraph does not affect existing legal and ethical obligations concerning maintenance and confidentiality of employee medical records. An employer's access is governed by existing federal, state and local laws and regulation. This standard, like Bloodborne Pathogens (29 CFR 1910.1030) and other OSHA standards, limits employer access to confidential information while allowing the employer access to the information needed to make appropriate decisions relative to his or her medical surveillance program. For example, paragraph (g)(7)(ii) limits the information that can be included in the physician's or other licensed health care professional's written opinion and paragraph (g)(7)(iii) requires that other medical diagnoses or findings be kept confidential. There is no language in this proposed standard that grants an employer access to the confidential information in an employee's medical file. OSHA illness and injury records are accessible under 29 CFR 1904 and 29 CFR 1960, as appropriate, to the facility. In this proposal, as in OSHA's other health standards, training records and engineering control maintenance and monitoring records are to be provided upon request to the employees, their representatives, the Director and the Assistant Secretary. Employers should not have difficulty complying with this provision because most will have experience with such recordkeeping from other standards. There are no confidentiality issues raised by these records.

In paragraph (i)(6), an employer who goes out of business is required to transfer medical records as set forth in 29 CFR 1910.1020(h) and 29 CFR 1904, which address the transfer of medical records. Specifically, medical records must be transferred to a successor employer who must accept them and keep them in accordance with the requirements of 29 CFR 1910.1020. In the event the employer ceases to do business and there is no successor employer, the employer is required to notify the Director, at least three months prior to disposal of the records, and transmit them to the Director if required by the Director to do so. This is consistent with other health standards and ensures that a successor employer (and the employees) can benefit from the information contained in the records. The reason the records are transferred (if requested) to the Director of NIOSH is that NIOSH has a vested interest in maintaining records of occupational injuries and illnesses and is in an excellent position to decide how the records can be best used to be of value to the exposed employee, subsequent employees in the field and OSHA. At NIOSH, the records remain confidential as required by 29 CFR 1910.1020(e). Thus, only the employee or his or her representative with the permission of the employee retains access to the medical records transferred to NIOSH.

Paragraph (j) Definitions

Acid-Fast Bacilli (AFB) means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria. Smears of sputum samples and other clinical specimens may be stained with dyes to detect acid-fast mycobacteria such as *M. tuberculosis.* However, AFB smear tests cannot distinguish one type of mycobacteria from another. Therefore, as noted by CDC, when AFB are seen on a stained smear of sputum or other clinical specimens, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis* (Ex. 4B).

Accredited Laboratory for purposes of this standard means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories. Under the medical surveillance provisions of the proposed standard, paragraph (g)(1)(iv) requires that all laboratory tests required by the standard be conducted by an accredited laboratory. This definition makes clear OSHA's intent about the type of laboratory that would be required to conduct these types of tests.

The term *AFB Isolation Room or Area* refers specifically to the rooms or areas where individuals with suspected or confirmed infectious TB are isolated. For purposes of this standard this term includes, but is not limited to, rooms, areas, booths, tents or other enclosures that are maintained at negative pressure relative to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.* Such rooms or areas are able to contain droplet nuclei through unidirectional airflow into the room (i.e., negative pressure). A definition of negative pressure is presented below and a more detailed explanation can be found in the Summary and Explanation of paragraph *(d), Work Practices and Engineering Controls.*

Air purifying respirator means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator. Air purifying respirators remove particular contaminants (e.g., particulates, organic vapors, acid gases) from the ambient air by drawing the air through appropriate filters, cartridges, of canisters.

Anergy means the inability of a person to react to skin test antigens (even if the person is infected with the organism(s)tested because of immunosuppression. More specifically, an anergic individual's immune system has become so compromised that it is unable to mount a sufficient reaction to the test organism. Because of their inability to respond immunologically, persons with anergy will have a negative tuberculin skin test even if they are infected with *M. tuberculosis.* Therefore, as noted by the CDC, it may be necessary to consider other epidemiologic factors (e.g., the proportion of other persons with the same level of exposure who have positive tuberculin skin test results and the intensity or duration of exposure to infectious TB patients that the anergic person experienced) when making a determination as to whether that anergic individual has been infected with *M. tuberculosis* (Ex. 4B). As discussed under paragraph (g)(2)(iii), Medical Surveillance, tuberculin skin testing is to include anergy testing when the physician or other licensed health care professional, as appropriate, determines such testing is necessary. Knowing which individuals are anergic will help to determine those situations where information other than skin test status will need to be ascertained and considered in order to assess the likelihood of infection for exposed employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative, and is a definition consistent across all OSHA standards.

BCG (Bacille Calmette-Guerin) vaccine means a tuberculosis vaccine used in many parts of the world. Because of its variable efficacy and its impact upon tuberculin skin tests (i.e., making skin test interpretation more difficult), routine BCG vaccination is not currently recommended in the

United States (Ex. 7–50). However, many foreign countries still use BCG as part of their tuberculosis control programs, especially for infants (Ex. 7–72). Since individuals vaccinated with BCG may have a tuberculin skin test that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*, it is helpful to know whether an individual has been vaccinated with BCG and when such vaccination occurred. Thus, under the medical surveillance provisions of the proposed standard, the medical history is to include a history of BCG vaccination.

Cartridge or canister means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container. With respect to this standard, respirators would be equipped with cartridges or canisters containing particulate filters.

Clinical laboratory has been defined for purposes of this standard as a facility or an 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. This definition is meant to apply to laboratories where routine diagnostic tests for TB are conducted as compared to research laboratories where *M. tuberculosis* may be cultured in large volumes or concentrated for research or commercial production. Clinical laboratories may be located within facilities such as hospitals or clinics, or they may be freestanding facilities.

Confirmed infectious tuberculosis (TB) means a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR); and the individual is capable of transmitting the disease to another person. The disease state may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei.

As discussed under the definition for AFB, a positive AFB smear indicates only that an individual has an identifiable mycobacterium. The three methods listed here provide positive confirmation of *M. tuberculosis*. In addition, the definition states that the disease state must be capable of being transmitted to another person (i.e., infectious). This provision of the definition is to differentiate this state of the disease from other active forms of TB disease where the individual is not infectious. For example, an individual may contract active TB disease and become infectious. After adequate drug therapy has been initiated the individual may become noninfectious, at which point he or she cannot transmit the disease to other individuals. However, the individual, while no longer infectious, still has active disease and must continue treatment for several months because living bacilli are still in his or her body. The definition also states that the disease may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei. In most cases, it is the pulmonary or laryngeal forms of infectious TB that present a risk of infection for other individuals. This is due to the fact that tuberculosis bacilli in the pulmonary or laryngeal tracts may be easily dispelled when infectious individuals cough or speak. Other body sites infected with the bacilli, i.e., extrapulmonary TB, do not present an infection hazard in most cases because the bacilli are not capable of being dispelled outside the body. However, in some situations, such as a lesion or an abscess where the infected tissue is exposed, there may be a risk of transmission of disease when certain procedures are performed (e.g., tissue irrigation) that could generate droplet nuclei containing the bacilli.

Conversion means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines. Under paragraph (g), the employer is required to provide medical management and follow-up to employees who have converted to positive tuberculin skin test status (e.g., providing preventive therapy, if appropriate, and conducting follow-up investigations of circumstances surrounding the conversion). Since a number of specific actions are required of the employer as a result of a conversion, it is necessary that conversions be correctly identified. An important part of this identification is the interpretation as to whether an employee has a positive skin test response. As such, this definition states that the interpretation of the positive reaction should be based upon current CDC guidelines (Ex. 4B). It is not OSHA's intent to define what should constitute a positive reaction, but rather to assure that such determinations are made using currently accepted public health guidelines.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative. Similar to the definition for Assistant Secretary, the definition for Director is consistent across OSHA standards.

Disposable respirator means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached. In general, the facepiece of these respirators is constructed from the particular filter media of interest (e.g., particulate filter).

Exposure incident for purposes of this standard means 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 of the applicable exposure control measures required by this section. This definition is limited to those situations involving exposure to an individual with confirmed infectious TB or air originating from an area where a source of aerosolized *M. tuberculosis* is present; it does not include exposure to individuals with suspected infectious TB. OSHA has limited the definition in this way because several provisions in the proposed standard are triggered by the occurrence of an exposure incident. For example, under paragraph *(g), Medical Surveillance*, the employer is required to provide additional tuberculin skin testing to each affected employee and to investigate and document the circumstances surrounding each exposure incident to determine if changes can be instituted to prevent similar occurrences in the future. OSHA believes that it would be burdensome and unnecessary for the employer to conduct follow-up investigations for those occurrences where an employee's exposure is to an individual suspected of having infectious TB but for whom infectious disease is subsequently ruled out.

An example of an exposure incident is an employee entering an AFB isolation room or area occupied by an individual with confirmed infectious TB without the employee wearing appropriate personal respiratory protection equipment. This occurrence would not be defined under the standard as an exposure incident if the individual in the AFB isolation room had only suspected infectious TB. If the individual in AFB isolation room was later confirmed to have infectious TB, the employee entering the isolation room without appropriate respiratory equipment would then be considered to have had an exposure incident and the required medical management and follow-up provisions for an exposure

incident under paragraph *(g), Medical Surveillance,* would be required.

Another example of an exposure incident is a failure of engineering controls, e.g., the ventilation system in an AFB isolation room housing an individual with confirmed infectious TB malfunctioned, negative pressure was lost, and air containing *M. tuberculosis* was dispelled into the hall corridor, exposing unprotected employees. Although OSHA would consider this type of loss of negative pressure in an AFB isolation room to be an exposure incident, the Agency does not intend that each opening of the door to an AFB isolation room be considered an exposure incident, even though some loss of negative pressure may result when the door to an AFB isolation room is opened. As a practical matter, OSHA believes it would be infeasible to consider every instance that a door to an isolation was opened as an exposure incident. In addition, these losses of negative pressure are generally small, if doors are kept open only briefly for purposes of entry and exit and are kept closed at all other times while the room is in operation for TB isolation as required under the Work Practices and Engineering Controls paragraph (d)(5)(vi).

There is a significant difference in the meaning of the terms ''exposure incident'' and ''occupational exposure'' as they are used in this standard. This difference is discussed further under the definition of ''occupational exposure''.

Filter means a component used in respirators to remove solid or liquid aerosols from the inspired air. The filter is the medium that captures the aerosol, preventing it from passing through to the respirator wearer.

Fit factor is a quantitative measure of the fit of a particular respirator on a particular individual. Fit factor is derived from the ratio of the concentration of a challenge agent (or air pressure) outside of the respirator to the concentration of the test agent (or air pressure) inside the respirator.

High Efficiency Particulate Air (HEPA) Filter means a specialized filter that is capable of removing 99.97 percent of particles greater than or equal to 0.3 micrometer in diameter.

High-hazard procedures are 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 induction of coughing or the generation of aerosolized *M. tuberculosis.* Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis.* The procedures listed above present a high hazard because they are performed on individuals with suspected or confirmed infectious TB or on specimens or deceased individuals where *M. tuberculosis* may be present. For example, some of the procedures listed above, such as bronchoscopies and pentamidine administration, cause people to cough. For individuals with pulmonary TB, coughing will increase the likelihood that they will generate aerosols with a high concentration of droplet nuclei. In addition, certain autopsy procedures, such as cutting into a lung containing *M. tuberculosis,* and certain laboratory procedures, such as processing infected tissue samples with pressurized freezants, can generate aerosols containing droplet nuclei. In the absence of *M. tuberculosis,* these procedures would not be high-hazard. For example, endotracheal intubation on an individual who does not have suspected or confirmed infectious TB would not be considered a high-hazard procedure.

M. tuberculosis means *Mycobacterium tuberculosis,* the scientific name of the bacillus that causes tuberculosis.

Negative Pressure means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. Paragraph (d)(5)(i) of Work Practices and Engineering Controls requires that negative pressure be maintained in all AFB isolation rooms or areas, and paragraph (d)(4) requires that all high-hazard procedures be performed in such rooms or areas. Maintaining negative pressure in such rooms or areas helps to assure that droplet nuclei are contained and not spread to other areas of the facility where unprotected employees may be exposed. A further discussion of this principle can be found in the Summary and Explanation of paragraph *(d), Work Practices and Engineering Controls.*

Negative pressure respirator means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator. In a negative pressure respirator, the wearer's inhalation creates a drop in pressure inside the facepiece, consequently drawing outside air through the filter and into the respirator.

Occupational exposure is one of the key terms upon which the proposed standard rests. It contains the criteria that trigger application of the standard for employees in work settings covered under the scope of the standard as listed in paragraphs (a)(1) through (a)(8) and for employees providing the care and services listed in paragraphs (a)(9) and (a)(10). Although a variety of work settings and several specific types of work are covered within the scope of the standard, it is only employees who have ''occupational exposure'' in those work settings and who are providing the particular services that must be given the protection mandated by the standard. The exception to this is that an employer covered under paragraph *(a), scope,* must provide medical management and follow-up to other employees who have an exposure incident.

For purposes of this standard, occupational exposure means reasonably anticipated contact, which 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.* An example of reasonably anticipated contact between an employee and an individual with suspected or confirmed infectious TB would be an admissions clerk working in a homeless shelter. In view of the high incidence of TB among the homeless, it can reasonably be anticipated that an employee screening people for admission into the shelter would have contact with a person with infectious TB during the performance of his or her job duties. Another, more obvious, example would be a bronchoscopist in a hospital that provides care for individuals with suspected or confirmed infectious TB. Others could include some physicians, nurses, paramedics and emergency medical technicians, health aides, prison guards, and intake workers in the facilities listed in paragraph (a) of this section. An example of an employee who would not be reasonably anticipated to have occupational exposure is an worker, in a covered facility, whose duties were limited to working in an area where suspected or confirmed TB patients or clients do not go and where the air would not contain aerosolized *Mycobacterium tuberculosis.* The risk of exposure for this employee is comparable to the exposure potential by the general population.

The term *occupational exposure* is used differently than the term *exposure incident* in the proposed standard. Occupational exposure is used to define

a condition of the employee's work and to identify which employees are affected in a way that can reasonably be anticipated, due to their job duties, to involve potential exposure to aerosolized *M. tuberculosis,* i.e., contact with an individual with suspected or confirmed infectious TB or with air that may contain aerosolized *M. tuberculosis.* The intent of the standard is to prevent exposure to aerosolized *M. tuberculosis;* therefore, certain proactive measures are required by the standard, e.g., training and medical surveillance, when occupational exposure is present. In order to provide these measures, it is necessary to identify which employees may be exposed *before* exposure occurs. The definition of ''occupational exposure'' is the basis for making this identification.

An *exposure incident,* on the other hand, is a discrete event in which it is known that an employee has had contact with aerosolized *M. tuberculosis,* i.e., with an individual with confirmed infectious TB or air containing aerosolized *M. tuberculosis.* The term ''exposure incident'' is used to define those occasions when certain reactive measures are required by the standard, such as medical management and follow-up. It is exposure to an individual with confirmed infectious TB that matters, since it is not necessary to take reactive measures after being exposed to an individual with suspected infectious TB if that individual has subsequently been determined not to have infectious TB.

Physician or Other Licensed Health Care Professional means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows her or him to independently perform or be delegated to perform some or all of the health care services required by paragraph (g) of this section. Paragraph (g) requires that all medical evaluations and procedures and medical management and follow-up be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA is aware that a variety of health care professionals are licensed by their respective states to legally perform different medical provisions required under this proposed standard. This definition clarifies that it is not OSHA's intent to dictate the specific type of health care professional to perform the activities required by the medical surveillance paragraph. OSHA's intent is merely that these activities be performed by persons who are legally permitted to independently perform or be delegated to perform some or all of the health care services required under the medical surveillance provisions of the standard. Employers wishing to use the services of a variety of health care providers must be familiar with the licensing laws of their state to ensure that the activities being performed are within the scope of that health care provider's licensure.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone. A PAPR uses a blower to draw ambient air through a filter and provide this filtered air, under pressure, to the facepiece of the wearer.

Qualitative fit test means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response. Generally, this assessment of adequacy of respirator fit is made by determining whether an individual wearing the respirator can detect the odor, taste, or irritation of a challenge agent introduced into the vicinity of the wearer's breathing zone.

Quantitative fit test means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator. Leakage can be assessed through means such as measuring the concentration of a challenge agent (or air pressure) outside of the respirator versus the concentration of the agent (or air pressure) inside the respirator. The ratio of the two measurements is an index of the leakage of the seal between the respirator facepiece and the wearer's face.

Research laboratory is defined as a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories. The purpose of this definition is to distinguish research laboratories from clinical laboratories. Under paragraph (e) of the proposed standard, research laboratories are required to meet additional provisions beyond those required for clinical laboratories (e.g., use of a hazard warning sign incorporating the biohazard symbol when materials containing *M. tuberculosis* are present in the laboratory and use of two sets of self-closing doors for entry into the work area from access corridors). These additional requirements are proposed due to the higher degree of hazard that may be present in research laboratories as a result of the presence of research materials that may contain *M. tuberculosis* in larger volumes and higher concentrations than would normally be found in diagnostic specimens or cultures in clinical laboratories.

Respirator means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants. While the term ''respirator'' may be used in medical situations to refer to a device that provides breathing assistance to an individual who is experiencing breathing difficulty, this section utilizes this term only in reference to the type of protective device defined above.

Suspected infectious tuberculosis means 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 active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Suspected infectious TB is another key term in the proposed standard. The presence of a person with suspected infectious TB triggers and is associated with a number of the provisions required of employers. Applying the criteria associated with suspected infectious TB is the first step in the early identification of individuals with infectious TB and is therefore a key factor in the elimination and minimization of occupational transmission of TB. Therefore, for purposes of implementing the standard it is important that what constitutes ''suspected infectious TB'' is clear.

The first criterion in identifying an individual as having suspected infectious TB is the presence of TB infection and the signs and symptoms of active TB. Under the second criterion, an individual would be suspected of having infectious TB if that individual had a positive AFB smear. The third criterion is based primarily on observation of an individual. The CDC states that:

* * * A diagnosis of TB may be considered for any patient who has a persistent cough (i.e., a cough lasting for ≥ 3 weeks) or other signs or symptoms compatible with active TB (e.g., bloody sputum, night sweats, weight loss, anorexia

or fever). * * * Diagnostic measures for identifying TB should be conducted for patients in whom active TB is being considered. These measures include obtaining a medical history and performing a physical examination, PPD skin test, chest radiograph, and microscopic examination and culture of sputum or other appropriate specimens. (Ex. 4B)

OSHA has relied on the CDC's list of symptoms, but does not agree that employers need only ''consider'' a TB diagnosis when any of the symptoms appear. The Agency believes that requiring employers merely to consider a TB diagnosis under these circumstances may allow too many individuals with infectious TB to slip through this screen and remain unidentified. In addition, the CDC recommendations do not identify the minimum number of signs or symptoms that should trigger employer concern. The problem with the CDC's approach is that the signs and symptoms are so general that they would be difficult to apply in many of the occupational exposure circumstances covered by the standard. For example, if OSHA required employers to identify each individual with even one of the signs or symptoms of TB as having suspected infectious TB, too many individuals would be likely to be identified, thereby wasting valuable health care resources. For these reasons, OSHA has proposed that employers be required to determine that an individual has suspected infectious TB when the individual has a prolonged cough and at least two of the other signs or symptoms of infectious TB. The Agency believes that requiring the employer to identify individuals as suspect cases when they have only a prolonged cough, which is the primary mode of transmission, and at least 2 other signs or symptoms strikes the appropriate balance between over inclusion and under inclusion, i.e., between considering almost every individual in poor health as a suspect case and missing individuals who should be suspected of having infectious TB. OSHA believes that setting forth these more definitive criteria will meet the needs of the many employers covered by this standard who will not have skilled medical persons making initial determinations about whether or not an individual has suspected infectious TB. Employer who are in a position to make medical determinations are permitted by the standard to rule out infectious TB by determining that a given individual's signs and symptoms are the result of a cause other than TB.

That an employer knows or with reasonable diligence should know that an individual meets one or more of these criteria means that an employer must utilize the means at his or her disposal to gather relevant information about the individual. For example, the employer may have access to the medical records of the individual or may question an individual who has signs or symptoms of TB in order to obtain information about the individual, such as skin test status, AFB smear status, and so forth. How much questioning the employer might do depends on the work setting. For example, a hospital will have intake procedures that include asking questions, as will most homeless shelters and other fixed work sites. In other work settings, such as the many places in which emergency medical services and home health care are provided to unidentified individuals with infectious TB, the employer's obligation will be to respond when an employee notices signs or symptoms compatible with TB. In many of these instances, it is the training employees receive in identifying individuals with suspected TB that will be the most important factor.

In addition, as noted above, an individual who meets one or more of the above criteria but whose condition has been medically determined to result from a cause other than TB need not be considered to have suspected infectious TB. For example, a physician or other licensed health care professional, as appropriate, could determine that the signs and symptoms exhibited by the individual were the result, for example, of pneumonia and not TB.

Tight-fitting respirator means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth while a full facepiece covers the nose, mouth, and eyes.

Tuberculosis (TB) means a disease caused by *M. tuberculosis*.

Tuberculosis infection means a condition in which living *M. tuberculosis* bacilli are present in the body, without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, the individual may have no symptoms related to the infection and may not be capable of transmitting the disease.

Tuberculosis disease is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

Tuberculin skin test means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of reaction induration. It is also referred to as a PPD skin test.

Two-step testing is a baseline skin testing procedure used to differentiate between a boosted skin test reaction and a skin test reaction that signifies a new infection. If the initial skin test is negative, a second skin test is administered 1 to 3 weeks later. If the second skin test is positive, the reaction is probably due to boosting. If the second skin test is negative, the individual is considered to be not infected. A subsequent positive skin test in this individual would thus indicate a new infection. Boosting is discussed in more detail in connection with the Medical Surveillance paragraph.

Paragraph (k) Dates

As proposed, the final rule would become effective ninety (90) days after publication in the **Federal Register**. This will allow time for public distribution and give employers time to familiarize themselves with the standard. The various provisions have phased-in effective dates.

The employer's initial duty under the standard is the exposure determination and establishment of the written Exposure Control Plan required by paragraph (c) of this section. The plan would need to be completed 30 days after the effective date.

Thirty days later, 60 days after the effective date, paragraphs (h)(3), Information and Training, (g) Medical Surveillance, and (i) Recordkeeping would take effect.

Ninety (90) days after the effective date, the work practice procedures and engineering controls required by paragraph (d) (in work settings other than those noted below), the respiratory protection required by paragraph (f), and the labels and signs required by paragraphs (h) (1) and (2) would take effect. The work practices that are directly related to the engineering controls would have to be implemented as soon as the engineering controls were functional. Finally, the requirements for clinical and research laboratories contained in paragraph (e) would also take effect 90 days after the effective date.

For businesses with fewer than 20 employees, the engineering controls required by paragraph (d) of this section would take effect 270 days after the effective date. As noted above, the work practices directly related to the engineering controls being installed in accordance with paragraph (d) of this section must be implemented as soon as the engineering controls are

implemented. Since engineering controls may necessitate more extensive planning than is required to comply with other provisions of the standard, OSHA is proposing an extended phase-in for the smallest employers.

Since many employers have many of these provisions already in effect through current infection control plans, OSHA believes that these dates provide adequate time for compliance. Nevertheless, OSHA seeks comment on the appropriateness of the dates for compliance with the various provisions of the standard.

XI. Public Participation—Notice of Hearing

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before December 16, 1997, and submitted in quadruplicate to the Docket Officer, Docket No. H–371, Room N2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Comments limited to 10 pages or less also may be transmitted by facsimile to (202) 219–5046, provided the original and three copies are sent to the Docket Officer thereafter.

Written submissions must clearly identify the provisions of the proposal that are being addressed and the position taken with respect to each issue. The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard will be provided at an informal public hearing scheduled to begin at 10:00 A.M. on February 3, 1998, in Washington, DC in the Auditorium of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice of Intention to Appear

All persons desiring to participate at the hearings must file in quadruplicate a notice of intention to appear postmarked on or before December 16, 1997 addressed to the Docket Officer, Docket No. H–371, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 219–7894. The Notice of Intention to Appear also may be transmitted by facsimile to (202) 219–5046, provided the original and 3 copies of the notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Docket Office, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The hearing site that the party is requesting to attend;

(3) The capacity in which the person will appear;

(4) The approximate amount of time requested for the presentation;

(5) The specific issues that will be addressed;

(6) A detailed statement of the position that will be taken with respect to each issue addressed;

(7) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(8) Whether the party wishes to testify on the days set aside to focus on homeless shelters.

Filing of Testimony and Evidence Before Hearings

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony, including any documentary evidence to be presented at the hearing to the Docket Officer at the above address. This material must be postmarked by December 31, 1997 and will be available for inspection and copying at the OSHA Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper notices of intention to appear will be entitled to ask questions and otherwise participate fully in the proceeding.

Conduct and Nature of Hearings

The hearings will commence at 10:00 a.m. on February 3, 1998. At that time any procedural matters relating to the proceeding will be resolved.

The nature of an informal hearing is established in the legislative history of section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15 (a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, the proceeding shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentations that can proceed expeditiously in the absence of rigid procedures that would impede or protract the rulemaking process.

Additionally, since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding, rather than an adjudicative one. The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The hearing will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who makes no recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911 and the prehearing guidelines, including the powers:

(1) To regulate the course of the proceedings;

(2) To dispose of procedural requests, objections, and comparable matters;

(3) To confine the presentation to the matters pertinent to the issues raised;

(4) To regulate the conduct of those present at the hearing by appropriate means;

(5) At the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

(6) At the Judges's discretion, to keep the record open for a reasonable, stated time to written information and additional data, views and arguments from any person who has participated in the oral proceeding.

Information on Homeless Shelter Issues for the Public Hearing

OSHA seeks to gather additional information related to homeless shelters during the written comment period and the public hearing. OSHA recognizes the unique service provided by homeless shelters, yet is also aware that shelters serve a client population that has been identified as possessing a high prevalence of active TB. OSHA is seeking information on all aspects of TB and employee protection against occupational transmission of TB in homeless shelters (e.g., means successfully being used by shelters to achieve early identification of shelter clients with suspected or confirmed infectious TB; successful programs currently being used to protect employees against occupational transmission of TB).

The Agency intends to designate a special session during the Washington, D.C. hearing to focus on the issues surrounding homeless shelters. We encourage hearing participants whose primary testimony will involve homeless shelters to indicate this in their Notice of Intention to Appear; OSHA will attempt to schedule these participants on the day(s) of the hearing set aside to focus on homeless shelters. Other participants whose testimony will not be primarily on homeless shelter issues but who wish to address the topic of homeless shelters will be scheduled another day, but they may enter a separate statement in the record during this period. In any case, participants are free to discuss homeless shelters or any other issue related to this proposed standard whenever they present their testimony.

Certification of Record and Final Determination After Hearing

Following the close of the posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all testimony and written submissions received as part of the record, and a standard will be issued based on the entire record of the proceeding, including the written comments and data received from the public.

List of Subjects

29 CFR Part 1910

Health professionals, Occupational safety and health, Reporting and recordkeeping requirements, Tuberculosis.

XII. Authority and Signature

This document was prepared under the direction of Greg Watchman, Acting Assistant Secretary of Labor, 200 Constitution Avenue, N.W., Washington, D.C., 20210.

It is issued under sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 1–90 (55 FR 9033) and 29 CFR Part 1911.

Signed at Washington, DC, this 15th day of September, 1997.

Greg Watchman,

Acting Assistant Secretary of Labor.

XIII. The Proposed Standard

General Industry

Part 1910 of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for Subpart Z of 29 CFR Part 1910 continues to read as follows and a new citation for § 1910.1035 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

Section 1910.1035 also issued under 29 U.S.C. 653.

* * * * *

2. Section 1910.1035 is added to read as follows:

§ 1910.1035 Tuberculosis

(a) Scope. This section applies to occupational exposure to tuberculosis (TB) occurring:

(1) In hospitals;

(2) In long term care facilities for the elderly;

(3) In correctional facilities and other facilities that house inmates or detainees;

(4) In hospices;

(5) In shelters for the homeless;

(6) In facilities that offer treatment for drug abuse;

(7) In facilities where high-hazard procedures (as defined by this section) are performed;

(8) In laboratories that handle specimens that may contain *M. tuberculosis,* or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of *M. tuberculosis;*

Note to paragraph (a)(8): Occupational exposure incurred in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section by temporary or contract employees or by personnel who service or repair air systems or equipment or who renovate, repair, or maintain areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is covered by this section.

(9) During the provision of social work, social welfare services, teaching, law enforcement or legal services if the services are provided in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section, or in residences, to individuals who are in AFB isolation or are segregated or otherwise confined due to having suspected or confirmed infectious TB.

(10) During the provision of emergency medical services, home health care and home-based hospice care.

(b) Application. An employer covered under paragraph (a) of this section, Scope (other than the operator of a laboratory), may choose to comply only with the provisions of appendix A to this section 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; and

(2) Has had no 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 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year.

(c) Exposure control—(1) *Exposure determination.* (i) Each employer who has any employee with occupational exposure shall prepare an exposure determination that contains the following:

(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.

(ii) The exposure determination shall be made without regard to the use of respiratory protection.

(2) *Exposure Control Plan.* (i) Each employer who has any employee with occupational exposure shall establish a written Exposure Control Plan that must include:

(A) The exposure determination required by paragraph (c)(1) of this section;

(B) Procedures for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions; and

(C) Procedures for reporting an exposure incident, including procedures specifying the individual to whom the incident is to be reported, and procedures for evaluating the circumstances surrounding the exposure incident.

(ii) Each employer who transfers individuals with suspected or confirmed infectious TB to a facility with AFB isolation capabilities shall include in the Exposure Control Plan procedures for prompt identification, masking or segregation, and transfer of such individuals.

Note to paragraph (c)(2)(ii): An employer's duties regarding transfer 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 facilities for the elderly, correctional facilities, and hospices may include contacting the receiving facility, providing transport, and taking other steps to ensure that the individual with suspected or confirmed infectious TB reaches the receiving facility. By contrast, the responsibilities of facilities that do not maintain custody over individuals, such as homeless shelters or facilities that offer treatment for drug abuse, might only include providing information about the receiving facility, contacting the facility, and providing directions to the facility.

(iii) Each employer in whose facility individuals with suspected or confirmed infectious TB are admitted or provided medical services shall include each of the following provisions in the Exposure Control Plan:

(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, including:

(*1*) Minimizing the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area (e.g., in an emergency room);

(*2*) Minimizing employee exposure in AFB isolation rooms or areas by combining tasks to limit the number of entries into the room or area and by minimizing the number of employees who must enter and minimizing the time they spend in the room or area;

(*3*) Delaying elective transport or relocation within the facility of an individual with suspected or confirmed infectious TB. Procedures are to be established to assure that, to the extent feasible, services and procedures for individuals with suspected or confirmed infectious TB are brought into or conducted in an AFB isolation room or area;

(*4*) Using properly-fitted masks (e.g., surgical masks, valveless respirators) on individuals with suspected or confirmed infectious TB or transporting such individuals in portable containment engineering controls when relocation or transport outside of AFB isolation rooms or areas is unavoidable. Procedures are to be established to assure that the individual is returned to an AFB isolation room or area as soon as is practical after completion of the service or procedure;

(*5*) Delaying elective high-hazard procedures or surgery until an individual with suspected or confirmed infectious TB is determined to be noninfectious;

(C) A list of all high-hazard procedures, if any, performed in the work setting; and

(D) A schedule for inspection, maintenance, and performance monitoring of engineering controls (see appendix E to this section).

(iv) Each employer who operates a laboratory shall include in the Exposure Control Plan a determination from the director of the laboratory as to whether the facility should operate at Biosafety Level 2 or 3 containment according to current CDC recommendations (CDC/NIH Biosafety in Microbiological and Biomedical Laboratories). The laboratory director shall determine and document the need for:

(A) Controlled access;

(B) Anterooms;

(C) Sealed windows;

(D) Directional airflow;

(E) Measures to prevent recirculation of laboratory exhaust air;

(F) Filtration of exhaust air before discharge outside; and

(G) Thimble exhaust connections for biological safety cabinets.

(v) Each employer who provides home health care or home-based hospice care shall include in the Exposure Control Plan procedures for prompt identification of individuals with suspected or confirmed infectious TB and procedures for minimizing employee exposure to such individuals; a list of the high-hazard procedures, if any, performed in the work setting; and procedures for delaying elective high-hazard procedures or surgery until the individual is noninfectious.

(vi) Each employer who claims reduced responsibilities related to paragraph (b), Application, or paragraph (g)(3)(iii)(D), Medical Surveillance, of this section shall document in the Exposure Control Plan the number of individuals with confirmed infectious tuberculosis encountered in the work setting in the past 12 months.

(vii) The Exposure Control Plan shall be:

(A) Accessible to employees in accordance with 29 CFR 1910.20(e);

(B) Reviewed at least annually and updated whenever necessary to reflect new or modified tasks, procedures, or engineering controls that affect occupational exposure and to reflect new or revised employee job classifications with occupational exposure; and

(C) Made available for examination and copying to the Assistant Secretary and/or the Director upon request.

(d) Work Practices and Engineering Controls. (1) Work practices and engineering controls shall be used to eliminate or minimize employee exposures to *M. tuberculosis.*

(2) The work practices in the Exposure Control Plan shall be implemented.

(3) Individuals with suspected or confirmed infectious TB shall be identified, and except in settings where home health care or home-based hospice care is being 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 as soon as possible thereafter.

(4) High-hazard procedures shall be conducted in an AFB isolation room or area.

(5) Engineering controls shall 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.

(i) Negative pressure shall be maintained in AFB isolation rooms or areas.

(ii) Negative pressure shall be qualitatively demonstrated (e.g., by smoke trails) daily while a room or area is in use for TB isolation (see appendix G to this section).

(iii) Engineering controls shall be maintained, and inspected and performance monitored for filter loading and leakage every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness (see appendix E to this section).

(iv) Air from AFB isolation rooms or areas shall be exhausted directly outside, away from intake vents, employees, and the general public. Air that cannot be exhausted in such a manner or must be recirculated must pass through HEPA filters before discharge or recirculation.

(v) Ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge.

(vi) Doors and windows of AFB isolation rooms or areas shall be kept closed while in use for TB isolation, except when doors are opened for entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure.

(vii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection (see appendix C to this section).

(6) The employer shall provide information about the TB hazard to any contractor who provides temporary or contract employees who may incur occupational exposure so that the contractor can institute precautions to protect his or her employees.

(e) Clinical and Research Laboratories. (1) This paragraph applies to clinical and research laboratories that engage in the culture, production, concentration, experimentation, or manipulation of *M. tuberculosis.* The requirements in this paragraph apply in addition to the other requirements of the standard.

(2) Clinical and research laboratories shall meet the following criteria:

(i) Standard microbiological practices.

(A) Procedures shall be performed in a manner that minimizes the creation of aerosols.

(B) Mouth pipetting shall be prohibited.

(C) Work surfaces and laboratory equipment shall be decontaminated at the end of each shift and after any spill of viable material.

(D) Cultures, stocks and other wastes contaminated with *M. tuberculosis* shall 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 shall be placed in a durable, leakproof container, closed and sealed for transport from the laboratory and labeled or color-coded in accordance with paragraph (h)(1)(ii) of this section.

(ii) *Special practices.* (A) Access to the laboratory shall be limited by the laboratory director when work with *M. tuberculosis* is in progress.

(B) A biosafety manual that includes procedures for spill management shall be adopted. The employer shall review the manual as necessary and at least annually. The employer shall update the biosafety manual as necessary to reflect changes in the work setting. Employees shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(C) Cultures, tissues, or specimens of body fluids contaminated with *M. tuberculosis* shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(D) All spills shall be immediately contained and cleaned up by employees who are properly trained and equipped to work with potentially concentrated *M. tuberculosis.* A spill or accident that results in an exposure incident shall be reported immediately to the laboratory director or other designated person.

(E) When materials containing or animals infected with *M. tuberculosis* are present in the laboratory or containment module, a hazard warning sign, in accordance with paragraph (h)(2)(iv), incorporating the universal biohazard symbol, shall be posted on all laboratory and animal room access doors.

(iii) *Containment equipment.* (A) Certified biological safety cabinets (Class 2) shall be used whenever procedures with a potential for generating aerosols of *M. tuberculosis* are conducted or whenever high concentrations or large volumes of *M. tuberculosis* are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened in a biological safety cabinet.

(B) Biological safety cabinets shall be certified when installed, annually thereafter, whenever they are moved, and whenever filters are changed.

(iv) Laboratory facilities. A method for decontamination of wastes contaminated with *M. tuberculosis* (e.g., autoclave, chemical disinfection, incinerator, or other decontamination system known to effectively destroy *M. tuberculosis*) shall be available within or as near as feasible to the work area.

(3) Research laboratories shall meet the following additional criteria:

(i) *Special practices.* (A) Laboratory doors shall be kept closed when work involving *M. tuberculosis* is in progress.

(B) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established so that only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(C) Respiratory protection shall be worn when aerosols cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(ii) *Containment equipment.* Certified biological safety cabinets (Class 2 or 3) or appropriate combinations of personal protection or physical containment devices, such as respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for manipulations of cultures and those clinical or environmental materials that may be a source of aerosols containing *M. tuberculosis;* aerosol challenge of animals with *M. tuberculosis;* harvesting of tissues or fluids from animals infected with *M. tuberculosis;* or the necropsy of animals infected with *M. tuberculosis.*

(iii) *Laboratory facilities.* (A) The laboratory shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors shall be required for entry into the work area from access corridors or other contiguous areas.

(B) Windows in the laboratory shall be closed and sealed.

(C) A ducted exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air from ''clean'' areas into the laboratory toward ''contaminated'' areas. The employer shall verify the proper direction of the airflow (i.e., into

the work area) 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.

(D) The high efficiency particulate air (HEPA)-filtered exhaust air from Class 2 or Class 3 biological safety cabinets shall be discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class 2 or 3 biological safety cabinets is to be discharged to the outside through the building exhaust air system, it shall be connected to this system in a manner (e.g., thimble units) that avoids any interference with the air balance of the cabinets or building exhaust system.

(E) Continuous flow centrifuges or other equipment that may produce aerosols shall be contained in devices that exhaust air through HEPA filters before discharge into the laboratory.

(f) Respiratory Protection—(1) *General.* (i) Each employer shall provide a respirator to each employee who:

(A) Enters an AFB isolation room or area in use for TB isolation;

(B) Is present during the 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 (e.g., ambulance, helicopter) or who transports an individual with suspected or confirmed infectious TB within the facility when 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); or

(F) Is working in a residence where an individual with suspected or confirmed infectious TB is known to be present.

(ii) Each employer who operates a research laboratory shall provide a respirator to each employee who is present when aerosols of *M. tuberculosis* cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(iii) The employer shall provide the respirator at no cost to the employee and shall assure that the employee uses the respirator in accordance with the requirements of this section.

(iv) The employer shall assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks set forth in paragraphs (f)(1)(i) and (f)(1)(ii) of this section and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

(2) *Respiratory Protection Program.* (i) 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) of this section shall establish and implement a written respiratory protection program that assures respirators are properly selected, fitted, used, and maintained. The program shall include the following elements:

(A) Procedures for selecting the appropriate 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) of this section, 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 respirator, as required under paragraph (h) of this section, Communication of Hazards and Training; and

(G) Procedures for periodically evaluating the effectiveness of the program.

(ii) The employer shall designate a person qualified by appropriate training or experience to be responsible for the administration of the respiratory protection program and for conducting the periodic evaluations of its effectiveness.

(iii) The employer shall review and update the written program as necessary to reflect current workplace conditions and respirator use.

(iv) The employer shall, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. A copy of the program shall be submitted to the Assistant Secretary and/or the Director, if requested.

(3) *Respirator Selection.* (i) The employer shall select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators shall 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.

(ii) The employer shall 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) of this section, the respirator shall be, at a minimum, either a HEPA respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration 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.

(4) *Respirator Use.* (i) The employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any condition that prevents such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or if facial hair interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal.

(ii) The employer shall assure that each employee who wears corrective glasses or goggles wears them in a manner that does not interfere with the seal of the facepiece to the face of the wearer.

(iii) Disposable respirators shall be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use.

(iv) The employer shall assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. The procedures in appendix B to this section or other procedures recommended by the respirator manufacturer that provide protection equivalent to that provided by the procedures in appendix B shall be used.

(v) Respirators shall be immediately repaired, or discarded and replaced, when they are no longer in proper working condition.

(vi) The employer shall permit each employee to leave the respirator use area as soon as practical to:

(A) Change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or

(B) Wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use.

(vii) Each employee required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section.

(viii) No employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be performed in accordance with paragraph (g)(5)(iii) of this section.

(5) *Fit Testing.* (i) The employer shall perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in appendix B to this section.

(ii) The employer shall assure that each employee who must wear a tight-fitting respirator passes a fit test:

(A) At the time of initial fitting;

(B) Whenever changes occur in the employee's facial characteristics which affect the fit of the respirator;

(C) Whenever a different size or make of respirator is used; and

(D) At least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section indicates that the annual fit test is not necessary.

(iii) When quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting half-mask respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber.

(6) *Maintenance and care of reusable and powered air purifying respirators.* (i) Respirators shall be cleaned and disinfected using the cleaning procedures recommended by the manufacturer at the following intervals:

(A) As necessary for respirators issued for the exclusive use of an employee; and

(B) After each use for respirators issued to more than one employee.

(ii) Respirators shall be inspected before each use and during cleaning after each use;

(iii) Respirator inspections shall include:

(A) A check of respirator function, tightness of connections and the condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and

(B) A check of the rubber or elastomer parts for pliability and signs of deterioration.

(iv) Respirators that fail to pass inspection shall be removed from service and shall be repaired or adjusted in accordance with the following:

(A) Repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer, and conducted by persons appropriately trained to perform such operations;

(B) Only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and

(C) Reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for adjustment or repair.

(v) Respirators shall be stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals and prevents deformation of the facepiece or exhalation valve.

(7) *Identification of filters, cartridges, and canisters.* (i) Filters, cartridges, and canisters used in the workplace shall be properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service.

(ii) The NIOSH approval label on a filter, cartridge, or canister shall not be intentionally removed, obscured, or defaced while it is in service in the workplace.

(8) *Respiratory protection program evaluation.* The employer shall review the overall respiratory protection program at least annually, and shall conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The review of the program shall include an assessment of each element required under paragraph (f)(2) of this section.

(g) Medical Surveillance—(1) *General.* (i) Each employer who has any employee with occupational exposure shall provide the employee with medical surveillance as described in this paragraph.

(ii) Each employer covered under paragraph (a), *Scope,* of this section shall provide information about the signs and symptoms of pulmonary TB, a medical history, a physical examination, TB skin testing, medical management and follow-up and, if indicated, other related tests and procedures, and medical removal protection if the employee develops infectious TB, to any of his or her employees who have an exposure incident while working in a covered work setting, even if such employee is not categorized as having occupational exposure.

(iii) Medical surveillance provisions, including examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:

(A) Provided at no cost to the employee;

(B) Provided at a reasonable time and place for the employee;

(C) Performed by or under the supervision of a physician or other licensed health care professional, as appropriate; and

(D) Provided according to recommendations of CDC current at the time these evaluations and procedures take place, except as specified by this paragraph (g).

(iv) Laboratory tests shall be conducted by an accredited laboratory.

(2) *Explanation of Terms.* This paragraph explains the terms used in paragraph (g).

(i) *Medical history* emphasizes the pulmonary system, and includes previous exposure to *M. tuberculosis,* BCG vaccination, TB skin test results, TB disease, prior and current preventive or therapeutic treatment, current signs or symptoms of active TB disease, and factors affecting immunocompetence;

(ii) *Physical examination* emphasizes the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence;

(iii) *TB skin testing,* includes anergy testing if indicated, and is only for employees whose TB skin test status is not known to be positive. An initial 2-step protocol is to be used for each employee who has not been previously skin tested and/or for whom a negative test cannot be documented within the past 12 months. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be utilized to fulfill the skin testing portion of this requirement. Periodic retesting shall be performed in accordance with paragraph (g)(3) of this section.

(iv) ''Determination of the employee's ability to wear a respirator'' is a face-to-face assessment of the health factors affecting respirator use and the need for the annual fit test.

Note to paragraph (g)(2)(iv): A determination of the need for the annual fit

test may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, for example, when a different size or make of respirator is used.

(v) ''Medical management and follow-up'' include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease.

(vi) *Other related tests and procedures* include those associated with TB infection and disease and determined to be necessary by the physician or other licensed health care professional, as appropriate.

(vii) Medical Removal Protection is the maintenance of earnings, seniority and other benefits specified in paragraph (g)(5) of this section for an employee who has confirmed or suspected infectious TB or is unable to wear a respirator.

(3) *Application*. (i) Each employee with occupational exposure shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A medical history and TB skin testing, and, if indicated, a physical examination and other related tests and procedures;

Note to paragraph (g)(3)(i)(A): If an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has the documented results of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The date(s) of the previous medical examination and skin test shall be used to determine the date(s) of the employee's next medical examination and skin test but in no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months.

(B) When the employee has signs or symptoms of TB, either observed or self-reported: A medical history, a physical examination, TB skin testing, medical management and follow-up, and, if indicated, other related tests and procedures;

(C) When an employee undergoes an exposure incident: A medical history, TB skin testing as soon as feasible (unless there is documented negative TB skin testing within the past 3 months), and if the result is negative, another skin test 3 months later, medical management and follow-up and, if indicated, a physical examination and other related tests and procedures;

(D) When the employee has a TB skin test conversion: A medical history, a physical examination, medical management and follow-up, and, if indicated, other related tests;

(E) Within 30 days of the termination of employment: A TB skin test; and

(F) At any other time the physician or other licensed health care professional, as appropriate, deems it necessary: Any or all the provisions of paragraph (g).

(ii) Each employee who must wear a respirator shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A determination of the employee's ability to wear a respirator; and

(B) When the wearer experiences unusual difficulty while being fitted or while using a respirator: A determination of the employee's ability to wear a respirator, including relevant components of a medical history, and, if indicated, a physical examination and other related tests and procedures.

(iii) An employee with negative TB skin test status shall be provided with a TB skin test every 6 months if the employee in the course of his or her duties:

(A) Enters an AFB isolation room or area;

(B) Performs or is present during the performance of high-hazard procedures;

(C) Transports or is present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle; or

(D) Works in an intake area where early identification procedures are performed (e.g., emergency departments, admitting areas) in facilities where six (6) or more individuals with confirmed infectious TB have been encountered in the past twelve months.

(4) *Additional Requirements.* (i) The employer shall assure that when the physician or other licensed health care professional, as appropriate, determines that an employee has suspected or confirmed infectious TB, the physician or other licensed health care professional, as appropriate, shall notify the employer and the employee as soon as feasible.

(ii) When the employer first identifies an individual with confirmed infectious TB, the employer shall notify each employee who has had an exposure incident involving that individual of his or her exposure to confirmed TB; and

(iii) When an exposure incident results in a TB skin test conversion, the employer shall assure that a determination is made of the drug susceptibility of the *M. tuberculosis* isolate from the source, unless the employer can demonstrate that such a determination is not feasible.

(iv) When an exposure incident or a TB skin test conversion occurs, the employer shall investigate and document the circumstances surrounding the exposure incident or conversion (e.g. failure of engineering controls or work practices and events leading to the exposure incident) to determine if changes can be instituted to prevent similar occurrences in the future.

(5) *Medical Removal Protection.* (i) Each employee with suspected or confirmed infectious TB shall be removed from the workplace until determined to be noninfectious.

(ii) For each employee who is removed from the workplace under paragraph (g)(5)(i) of this section, the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status, as if the employee had not been removed from the employee's job or otherwise medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first.

(iii) For each employee who is removed from his or her job under paragraph (f)(4)(viii), Respiratory Protection, of this section the employer shall 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. The employer shall 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.

(iv) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(6) *Information Provided to Physician or Other Licensed Health Care Professionals.* (i) Each employer shall assure that all physicians or other licensed health care professionals responsible for making determinations and performing procedures as part of the medical surveillance program are

provided a copy of this regulation and, for those employees required to wear respirators under this section, information regarding the type of respiratory protection used, a description of the work effort required, any special environmental conditions (e.g., heat, confined space entry), additional requirements for protective clothing and equipment, and the duration and frequency of usage of the respirator.

(ii) Each employer shall assure that the physician or other licensed health care professional, as appropriate, who evaluates an employee after an exposure incident is provided the following information:

(A) A description of the exposed employee's duties as they relate to the exposure incident;

(B) Circumstances under which the exposure incident occurred;

(C) Any diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure which could assist in the medical management of the employee; and

(D) All of the employee's medical records relevant to the management of the employee, including tuberculin skin testing results.

(7) *Written Opinion.* (i) Each employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section.

(ii) The written opinion shall be limited to the following information:

(A) The employee's TB skin test status;

(B) The employee's infectivity status;

(C) A statement that the employee has been informed of the results of the medical evaluation;

(D) A statement that the employee has been told about any medical conditions resulting from exposure to TB that require further evaluation or treatment;

(E) Recommendations for medical removal or work restrictions and the physician's or other licensed health care professional's opinion regarding the employee's ability to wear a respirator.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(h) Communication of Hazards and Training—(1) *Labels.* (i) Air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be labeled ''Contaminated Air—Respiratory Protection Required.'' The label shall be placed at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and discharge outlets of non-HEPA filtered direct discharge systems.

(ii) Clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory shall be labeled with the biohazard symbol or placed in a red container(s).

(2) *Signs.* (i) Signs shall be posted at the entrances to:

(A) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB;

(B) Areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB; and

(C) Clinical and research laboratories where *M. tuberculosis* is present.

(ii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9% (see Appendix C to this section).

(iii) Signs for AFB isolation rooms or areas, except as required in paragraph (h)(2)(iv) of this section, shall be readily observable and shall bear the following legend with symbol and text in white on a red background:

BILLING CODE 4510–26–P

BILLING CODE 4510–26–C

No Admittance Without Wearing a Type N95 or More Protective Respirator

Note to paragraph (h)(2)(ii): Employers may include additional information on signs provided it does not interfere with conveyance of this message.

(iv) Signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* shall include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation *Mycobacterium tuberculosis*, and special requirements for entering the laboratory or autopsy room.

(3) *Information and Training.* (i) Each employer shall assure that each employee with occupational exposure participates in a training program, which must be provided at no cost to the employee and be made available at a reasonable time and place.

(ii) Training shall be provided as follows:

(A) Before initial assignment to tasks where occupational exposure may occur;

(B) Within 60 days after the effective date of the standard; and

(C) At least annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii) of this section. The employer must provide re-training to the employee in any topic(s) in which specific knowledge and skills cannot be demonstrated.

Note to paragraph (h)(3)(ii): Training in the general topics under paragraph (h)(3)(vii) of this section which has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics under paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h).

(iii) For employees who have received training on TB in the year preceding the effective date of the standard, only training with respect to the provisions of the standard that were not included in such training need be provided. The annual retraining shall be conducted within one year from the date of the training that occurred before the effective date of the standard.

(iv) Annual training for each employee shall be provided within one calendar year of the employee's previous training.

(v) The employer shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new or modified exposures.

(vi) Material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.

(vii) The training program shall include an explanation of:

(A) The contents of this standard and the location of an accessible copy of the regulatory text of this standard;

(B) The general epidemiology of TB, including Multidrug-Resistant TB (MDR–TB), and the potential for exposure within the facility; the signs and symptoms of TB, including the difference between tuberculosis

infection and tuberculosis disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase the employee's risk of developing TB disease if infected (e.g., HIV infection, prolonged corticosteroid therapy, other immunocompromising conditions);

(C) The employer's exposure control plan and respiratory protection program and the means by which the employee can review the written plans;

(D) The tasks and other activities that may involve exposure to *M. tuberculosis*;

(E) The use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, respiratory protection, and site-specific control measures;

(F) Why a respirator is necessary, and the basis of selection of the respirators used, the types of respirators used, upkeep and storage of the respirators used, and their location and proper use, including procedures for inspection, donning and removal, checking the fit and seals, and wearing the respirator. This instruction shall allow sufficient practice to enable the employee to become thoroughly familiar with and effective in performing these tasks;

(G) The employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program;

(H) The procedures to follow if an exposure incident occurs, including the method of reporting the incident and the medical management and follow-up that the employer is required to provide, and the benefits and risks of prophylaxis; and

(I) The procedures to follow if the employee develops signs or symptoms of TB disease.

(viii) The person(s) conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) The employer shall provide employees with an opportunity for interactive questions and answers with the person conducting the training session.

(i) Recordkeeping—(1) *Medical Records.* (i) Each employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name, social security number, and job classification of the employee;

(B) A copy of all results of examinations; medical testing, including the employee's tuberculin skin test status; and follow-up procedures;

(C) The employer's copy of the physician's or other licensed health care professional's written opinion; and

(D) A copy of the information provided to the physician or other licensed health care professional.

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (i) are:

(A) Kept confidential; and

(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace, except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (i)(1) for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020. The medical records of employees who have worked for less than one year for the employer need not be retained beyond the term of employment if they are provided to the employee upon termination of employment.

(2) *OSHA Illness and Injury Records.* The employer shall record TB infection or disease in accordance with 29 CFR 1904 and 29 CFR 1960, as applicable.

(3) *Training Records.* (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The name and job classification of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(4) *Engineering Control Maintenance and Monitoring Records.* (i) Engineering control maintenance records shall include the following information:

(A) Date;

(B) Equipment identification;

(C) Task performed; and

(D) Sign-off.

(ii) Performance monitoring records shall include the following information:

(A) Date and time;

(B) Location;

(C) Parameter measured, including units when appropriate;

(D) Results of monitoring; and

(E) Sign-off.

(iii) Engineering control maintenance and monitoring records shall be maintained for three years.

(5) *Availability.* (i) Employee medical records required by paragraph (i)(1), Recordkeeping, of this section shall be provided upon request for the examination and copying to the subject employee, to anyone having the written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020. OSHA Illness and Injury Records shall be accessible under the provisions of 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) Employee training records required by paragraph (i)(3), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, to their representatives, to the Director, and to the Assistant Secretary.

(iii) Engineering control maintenance and monitoring records required by paragraph (i)(4), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, their representatives, to the Director, and to the Assistant Secretary.

(6) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h) and 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least three months before their disposal and transmit them to the Director, if required by the Director to do so, within the three month period.

(j) *Definitions.* For the purposes of this section, the following shall apply:

Acid-fast bacilli (AFB) means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria.

Accredited laboratory means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

Air-purifying respirator means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator.

AFB isolation room or area includes, but is not limited to, rooms, areas, booths, tents, or other enclosures that are maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.*

Anergy means the inability of a person to react to skin test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

BCG (Bacille Calmette-Guerin) vaccine is a tuberculosis vaccine.

Canister or *cartridge* means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container.

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.

Confirmed infectious tuberculosis is a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR). The disease state must be capable of being transmitted to another individual (e.g., pulmonary or laryngeal TB or extrapulmonary TB where the infected tissue is exposed and could generate droplet nuclei).

Conversion means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Disposable respirator means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached.

Exposure incident means 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 applicable exposure control measures required by this section.

Filter means a component used in respirators to remove solid or liquid aerosols from the inspired air.

Fit factor means a quantitative measure of the fit of a particular respirator on a particular individual.

High efficiency particulate air (HEPA) filter means a specialized filter that is capable of removing 99.97% of particles greater than or equal to 0.3 micrometer in diameter.

High hazard procedures are 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.* Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis.*

M. tuberculosis means *Mycobacterium tuberculosis,* the scientific name of the bacillus that causes tuberculosis.

Negative pressure means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas.

Negative pressure respirator means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

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.*

Physician or other licensed health care professional means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (g) of this section.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone.

Qualitative fit test means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response to a challenge agent.

Quantitative fit test means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Research laboratory is a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories.

Respirator means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants.

Suspected infectious tuberculosis means 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 active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Tight-fitting facepiece means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth; a full facepiece covers the nose, mouth, and eyes.

Tuberculosis (TB) means a disease caused by *M. tuberculosis.*

Tuberculosis infection means a condition in which living *M. tuberculosis* bacilli are present in the body without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, he or she may have no symptoms related to the infection and may not be capable of transmitting the disease.

Tuberculosis disease is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

Tuberculin skin test means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis.* The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of the reaction induration. It is also referred to as a PPD skin test.

Two-step testing is a baseline skin testing procedure used to identify a boosted skin test reaction from that of a new infection. The procedure involves placing a second skin test 1 to 3 weeks after an initial negative test. A positive reaction on the second test indicates a boosted reaction.

(k) Dates.—(1) *Effective Date.* The standard shall become effective on [insert date 90 days after publication of final rule in the **Federal Register**].

(2) *Start-up dates.* (i) *Exposure control.* The exposure control provisions required by paragraph (c) of this section shall take effect on [insert date 30 days after effective date of final rule].

(ii) The *Information and Training* provisions required under paragraph (h)(3), the *Medical surveillance* provisions required by paragraph (g), and the *Recordkeeping* provisions required by paragraph (i) of this section shall take effect on [insert date 60 days after effective date of final rule].

(iii) *Work practices and Engineering controls.* The work practice and engineering control provisions required by paragraph (d) of this section shall take effect on [insert date 90 days after effective date of final rule]. For businesses with fewer than 20 employees, engineering controls required by paragraph (d) of this section shall take effect [insert 270 days after effective date of final rule]. Work practice controls that are directly related to engineering controls being installed in accordance with this paragraph shall be implemented as soon as those engineering controls are implemented.

(iv) *Respiratory protection.* Respiratory protection provisions required by paragraph (f) of this section shall take effect on [insert date 90 days after effective date of final rule].

(v) *Labels and signs.* The labels and signs provisions required by paragraphs (h)(1) and (h)(2) of this section shall take effect on [insert date 90 days after effective date of final rule].

(vi) *Clinical and research laboratories.* The additional requirements for Clinical and Research Laboratories contained in paragraphs (e)(1) through (e)(3) shall take effect on [insert date 90 days after effective date of final rule].

Appendix A to § 1910.1035—Provisions for Employers Claiming Reduced Responsibilities Under Paragraph (b), Application (Mandatory)

(c) Exposure Control

Paragraph (c)(1)(i & ii) Exposure Determination
(c)(2)(i) Written Exposure Control Plan with the following elements:
(c)(2)(i)(A) The exposure determination
(c)(2)(i)(B) Procedures for providing information to employees about individuals identified with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized M. tuberculosis
(c)(2)(i)(C) Procedures for reporting an exposure incident
(c)(2)(ii) Procedures for identifying, masking or segregating and transferring individuals with suspected or confirmed infectious TB
(c)(2)(vi) Documentation of the number of individuals with confirmed infectious TB encountered in the past 12 months
(c)(2)(vii) (A–C) Accessible exposure control plan, reviewed annually and updated as necessary, and made available to the Assistant Secretary and Director

(d) Work Practice Procedures and Engineering Controls

(d)(1) Use of work practices to eliminate or minimize employee exposure
(d)(2) Implementation of the work practice procedures in the exposure control plan
(d)(3)(i) Identification and masking or segregating of individuals with suspected or confirmed infectious TB
(d)(3)(ii) Temporary isolation of individuals who cannot be transferred within 5 hours
(d)(5)(i–vii) Engineering controls if temporary isolation is used
(d)(6) Provide information about TB hazards to temporary or personnel who may incur occupational exposure

(g) Medical Surveillance

(g)(1)(i–iv) Medical surveillance program for each employee with occupational exposure or who has an exposure incident in one of the covered work settings, at no cost, at a reasonable time, by a physician or other licensed health care professional, according to current recommendations of the CDC and with laboratory tests conducted by an accredited laboratory
(g)(2)(i, ii, iii, v, vi & vii) Explanation of terms: Medical history, Physical examination, tuberculin skin testing, medical management and follow-up, medical removal protection, and other related tests and procedures
(g)(3)(i)(A) Initial TB skin testing and medical history (NOTE: Annual skin testing and medical histories are not required)
(g)(3)(i)(B) Medical history, TB skin testing and follow-up for employees who develop signs or symptoms of TB
(g)(3)(i)(C) Medical history, TB skin testing and medical management and follow-up of employees after an exposure incident
(g)(4)(i) Notification of employee and employer as soon as feasible about infectious TB disease status of the employee
(g)(4)(ii) Notification of employees about previously unidentified individuals with infectious TB
(g)(4)(iii) Determination of drug susceptibility of *M. tuberculosis* source after an exposure incident
(g)(4)(iv) Investigations of exposure incidents and TB skin test conversions
(g)(5)(i, ii & iv) Medical removal and protection of benefits for individuals with infectious TB
(g)(6)(i & ii) Information provided to the physician or other licensed health care professional
(g)(7)(i–iii) Physician or other licensed health care professional's written opinion

(h) Communication of Hazards and Training

(h)(1)(i) If temporary isolation is used, label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(h)(2)(i)(A) If temporary isolation is used, post signs at entrance to temporary isolation
(h)(2)(ii) When temporary isolation room or area is vacated by an individual with suspected or confirmed infectious TB, ventilate for an appropriate period
(h)(2)(iii) Signs for temporary isolation rooms or areas must have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''
(h)(3)(i–viii) Annual training with specified elements for employees with occupational exposure

(i) Recordkeeping

(i)(1)(i–iv) Medical Records
(i)(2) OSHA Illness and Injury Records
(i)(3)(i & ii) Training Records
(i)(4)(i–iii) If temporary isolation is used, engineering control maintenance records
(i)(5)(i & ii) Availability of medical and training records
(i)(6)(i & ii) Transfer of records

(k) Dates

(k)(1) Effective date
(k)(2)(i, ii & iii) Start up dates for exposure control, medical surveillance, information and training, recordkeeping, and work practices and engineering controls

Appendix B to § 1910.1035—Fit Testing Procedures (Mandatory)

Part I. Approved Fit Test Protocols

A. Fit Testing Procedures

The employer shall conduct fit testing using the following procedures. These provisions apply to both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a selection of respirators of various sizes and models.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he or she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted; the most acceptable mask is donned

and worn at least five minutes to assess acceptability. Assistance in assessing acceptability can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of acceptability shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the acceptability of the respirator:

(a) Position of the mask on the nose,

(b) Room for eye protection,

(c) Room to talk;

(d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described in this appendix or other fit check procedures recommended by the respirator manufacturer providing equivalent protection to the procedures in this appendix. Before conducting the negative or positive pressure fit checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns that cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. *Exercise regimen.* Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. *Test Exercises.* The test subject shall perform exercises, in the test environment, while wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with fit, in the manner described below:

(a) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally.

(b) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) *Moving head up and down.* Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) *Grimace.* The test subject shall grimace by smiling or frowning. (Only for QNFT testing, not performed for QLFT)

(g) *Bending over.* The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) *Normal breathing.* Same as exercise (a). Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate, by itself, for fit testing particulate respirators. If chosen for use in fit testing particulate respirators, the respirator must be equipped with an organic vapor cartridge, provided the employee will be using the same facepiece in the work setting except that it will be equipped with particulate filters.

(a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) *Isoamyl acetate fit test.* (1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot

diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent the test medium that is not contained will be removed from the general room air.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When the subject wearing the respirator passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self sealing bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as the DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as the DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 13 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. Bitrex (Denatonium benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because of its current acceptance and past validation. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening. The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # 14 and # 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 13.5 milligrams of Bitrex in 100 ml of 5% NaCl solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex in 200 ml of a 5% solution of NaCl in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A.13 of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

5. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate filters (i.e., HEPA, N100, R100, or P100) .

(b) No form of test enclosure or hood for the test subject shall be used.

(c) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties.

(d) Break both ends of a ventilation smoke tube containing stannic chloride. Attach one end of the smoke tube to an aspirator squeeze bulb and cover the other end with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(e) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his or her eyes closed while the test is performed.

(f) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject beginning at least 12 inches from the facepiece and gradually moving to within one inch, moving around the whole perimeter of the mask.

(g) The exercises identified in section I.A. 13 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(h) Each test subject passing the smoke test without evidence of a response (involuntary cough) shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he or she reacts to the smoke. Failure to evoke a response shall void the fit test.

(i) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable:

(1) Quantitative fit testing using a non-hazardous challenge aerosol (such as corn oil or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.

(2) Quantitative fit testing using ambient aerosol as the challenge agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit.

(3) Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean, maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Protocol

(a) *Apparatus.* (1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil or sodium chloride) or gases or vapors as test aerosols shall be used for quantitative fit testing.

(2) *Test chamber.* The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter (i.e., HEPA, N100, R100, P100) supplied by the same manufacturer in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used, provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(7) The test set-up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and

of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency or sorbent) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

(b) *Procedural Requirements.* (1) When performing the initial positive or negative pressure fit check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these fit checks.

(2) An abbreviated screening QLFT test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another method that can be used to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable challenge concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable fit typical of normal use.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(c) *Calculation of fit factors.* (1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(2) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 8 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak penetration method, which is the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise also meet the requirements of the average peak penetration method.

(ii) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(iii) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise is another method. This includes computerized integration.

(iv) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor is also appropriate. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercise 1,2,3, etc.

(4) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(5) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced if there is any indication of breakthrough by a test agent.

3. Ambient Aerosol Condensation Nuclei Counter (CNC) Protocol

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, model, and size that is intended to be used and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer TSI also provides probe attachments (TSI sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The Agency does not recommend the use of homemade sampling adapters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Portacount Fit Test Requirements.

(1) Check the respirator to make sure the respirator is fitted with a high efficiency filter (i.e., HEPA, N100, R100, P100) and that the sampling probe and line are properly attached to the facepiece.

(2) Instruct the person to be tested to don the respirator several minutes before the fit test starts. This purges the particles inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual should have already been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendencies for the respirator to slip; Self-observation in a mirror to evaluate fit; and respirator position.

(4) Have the person wearing the respirator do a fit check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same type of respirator.

(5) Follow the instructions for operating the Portacount and proceed with the test.

(b) *Portacount Test Exercises*—(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution so as not to hyperventilate.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute.

(6) *Grimace.* The test subject shall grimace by smiling or frowning for 15 seconds.

(7) *Bending Over.* The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist.

(8) *Normal Breathing.* Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(c) *Portacount Test Instrument.* (1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) A record of the test needs to be kept on file assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

4. Controlled Negative Pressure (CNP) Protocol

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator.

The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Dynatech Nevada also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his or her breath, then an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the challenge pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator.

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) *CNP Fit Test Requirements*—(1) The instrument shall have a non-adjustable challenge pressure of 15.0 mm water pressure.

(2) The CNP system defaults for challenge pressure shall be tested at −0.58 inches of water and the modeled inspiratory flow rate shall be 53.8 liters per minute.

Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The test subject shall be trained to hold his or her breath for at least 20 seconds.

(6) The test subject shall don the test respirator without any assistance from the individual who conducts the CNP fit test.

(7) The QNFT protocol shall be followed according to section I.C.1 except that the CNP test exercises shall be used.

(b) *CNP Test Exercises*—(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution not to hyperventilate. After the deep breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject needs to hold head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full down and hold his or her breath for 10 seconds during test measurement.

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) *Grimace.* The test subject shall grimace by smiling or frowning for 15 seconds. After the grimace exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(7) *Bending Over.* The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) *Normal Breathing.* Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) *CNP Test Instrument.*—(1) The test instrument shall have an effective audio warning device when the test subject fails to hold his or her breath during the test. The test shall be terminated whenever the test subject failed to hold his or her breath. The test subject may be refitted and retested.

(2) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

Part II. Facepiece Fit Checks (Nonmandatory)

A. *Positive pressure check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold

the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

Appendix C to § 1910.1035—Ventilation Chart for Isolation Rooms or Areas (Mandatory)

Under paragraph(d)(5)(vii), the proposed standard requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection. The following appendix is an excerpt of the CDC recommendations of the air changes per hour (ACH) and time in minutes required for removal efficiencies of 90%, 99% and 99.9% of airborne contaminants (Ex.4B). This table specifies the time necessary to ventilate an isolation room or area, for a given air change per hour, before allowing employees to enter without respiratory protection.

Minutes required for a removal efficiency of:

ACH	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

This table has been adapted from the formula for the rate of purging airborne contaminants. (Ex. 5–100) Values have been derived from the formula $t_1 = [In (C_2 + C_2) + (Q + V)] \times 60$, with $t_1 = 0$ and $C_1 + C_2$—(removal efficiency + 100), and where:

t_1 = initial timepoint
C_1 = initial concentration of contaminants
C_2 = final concentration of contaminants
Q = air flow rate (cubic feet per hour)
V = room volume (cubic feet)
Q + V = ACH

The times given assume perfect mixing of air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor (Ex. 5–99). The required time is derived by multiplying the appropriate time for the table by the mixing factor that has been determined for the booth or room. The factor and required time should be included in the operating instructions provided by the manufacturer of the booth or enclosure, and these instructions should be followed.

Appendix D to § 1910.1035—Ultraviolet Radiation Safety and Health Provisions (Nonmandatory)

This appendix sets forth non-mandatory guidelines on safety and health provisions concerning the use of ultraviolet germicidal irradiation (UVGI). Because the effectiveness of UVGI systems will vary, and the interaction of factors such as humidity, UV intensity, duration of exposure, lamp placement, and air mixing have not been adequately evaluated, employers may choose to use UVGI systems as supplements to the administrative, engineering, and work practice controls required by this standard. OSHA does not consider UVGI as a substitute or replacement for:

(1) Negative pressure;

(2) Exhaust of contaminated air directly to the outside away from intake vents and employees;

(3) High efficiency particulate air (HEPA) filtration of contaminated air before being recirculated to the general facility or exhausted directly outside (permitted only when it cannot be safely discharged).

UVGI Systems

The intent of UVGI systems is to kill or inactivate airborne microorganisms, including *M. tuberculosis.* Two types of systems are generally employed for this purpose: duct irradiation systems, and upper room air irradiation systems. (Floor level UVGI systems are used in some laboratory facilities, but are not specifically discussed in this appendix.) UVGI systems utilize low-pressure mercury vapor lamps that emit radiant energy predominantly at a wavelength of 254 nanometers (nm).[1] In duct irradiation systems, one or more UV tubes are positioned within a duct to irradiate air being exhausted from a room or facility. In upper room air irradiation systems, UV lamps are suspended from a ceiling or mounted on a wall. The lamps are positioned such that air in the upper part of the room is irradiated. The intent is to minimize the levels of UV radiation in the lower part of the room where the occupants are located. These systems rely on air mixing to move the air from the lower portion of the room to the upper portion of the room where it can be irradiated.

Safety and Health Considerations

UV radiation at 254 nm is absorbed by the outer surfaces of the eyes and skin. Overexposure to UVGI can result in photokeratitis (inflammation of the cornea) and/or conjunctivitis (inflammation of the conjunctiva).[2] Keratoconjunctivitis is a reversible condition but can be debilitating while it runs its course. Because there is a latency period before health effects are observed, workers may not recognize this as an occupational injury. Symptoms may include a feeling of sand in the eyes, tearing, and sensitivity to light. Overexposure of the skin to UVGI also can result in erythema (reddening). This effect is also reversible, with recovery occurring within 2 to 3 days.

In 1992, the International Agency for Research on Cancer (IARC) classified UV–C radiation as ''probably carcinogenic to humans (Group 2A)''.[3] This classification was based on studies suggesting that UV–C radiation can induce skin cancers in animals, DNA and chromosome damage in human cells in vitro, and DNA damage in mammalian skin cells in vivo. In the animal studies, exposure to UV–B could not be excluded; however, the observed effects were greater than expected for UV–B alone.[3] Laboratory studies have shown that UV radiation can activate human immunodeficiency virus (HIV) gene promoters in human cells (genes in HIV that prompt replication of the virus); however, the implications of these findings for humans exposed to UVGI are unknown.[4,5,6,7,8,9]

Occupational Exposure Criteria for Ultraviolet Radiation

In 1972, the National Institute for Occupational Safety and Health (NIOSH) published a recommended exposure limit (REL) for UV radiation to prevent adverse effects on the eyes and skin.[2] The NIOSH REL for UV radiation is wavelength dependent because different wavelengths of ultraviolet radiation have differing abilities to cause skin and eye effects. The American Conference of Governmental Industrial Hygienists (ACGIH) also has a Threshold Limit Value® for UV radiation that is identical to the REL in this spectral region.[10] It should be noted that photosensitive individuals and those concomitantly exposed to photosensitizing agents (including certain medications) may not be protected by these occupational exposure limits.[10]

The term relative spectral effectiveness is used to compare UV sources with a source producing UV radiation only at 270 nm, the wavelength of maximum sensitivity for corneal injury. For example, the relative spectral effectiveness (S_λ) at 254 nm is 0.5; therefore, twice as much energy is required at 254 nm to produce the same biological effect at 270 nm. Thus, at 254 nm, the NIOSH REL is 0.006 joules per square centimeter (J/cm^2), and at 270 nm it is 0.003 J/cm^2.

For germicidal lamps, proper use of the REL (or TLV) requires that the measured irradiance level (E) in microwatts per square centimeter (μW/cm^2) be multiplied by the relative spectral effectiveness at 254 nm (0.5) to obtain the effective irradiance (E_{eff}). The maximum permissible exposure time (t) for workers with unprotected eyes and skin can then be read directly from Table 1 for selected values of E_{eff}, or can be calculated (in seconds) by dividing 0.003 J/cm^2 (the NIOSH REL at 270 nm) by E_{eff} in W/cm^2. To protect workers who are exposed to germicidal UV radiation for eight hours per day, the measured irradiance (E), should be $\leq$0.2 μW/cm^2. This is calculated by using Table 1 to obtain E_{eff} (0.1 μW/cm^2), and then dividing by S_λ (0.5).

Example: If the measured irradiance was 0.4 μW/cm^2, then the maximum permissible exposure time is 15,000 seconds, or approximately 4 hours as shown below:

$$E_{eff} = E \times S_{\lambda}$$
$$= 0.4\ \mu W/cm^2 \times 0.5$$
$$= 0.2\ \mu W/cm^2$$
$$t\,(sec) = \frac{0.003\ J/cm^2}{E_{eff}\left(W/cm^2\right)}$$
$$= \frac{0.003\ J/cm^2}{0.2 \times 10^{-6}\ W/cm^2}$$
$$= 15{,}000\ sec.\ (approx\ 4\ hours)$$

TABLE 1—MAXIMUM PERMISSIBLE EXPOSURE TIMES FOR SELECTED VALUES OF E_{eff}.

Duration of exposure per day	Effective irradiance E_{eff} ($\mu W/cm^2$)
8 hrs	0.1
4 hrs	0.2
2 hrs	0.4
1 hr	0.8
30 min	1.7
15 min	3.3
10 min	5.0
5 min	10.0

This table was adapted from a table in *Criteria for a Recommended Standard . . . . Occupational Exposure to Ultraviolet Radiation.*[2] Maximum permissible exposure times refer to workers with unprotected eyes and skin.

Measurement Equipment. A UV radiometer can be used to measure the irradiance levels in the room and to document lamp output. Some UV measurement systems rely on the use of a detector or probe which is most sensitive at 254 nm, while others rely on the use of a broad-band radiometer with an actinic probe. The latter instrument has a response that accounts for the wavelength dependence of the REL, allowing direct measurement of the effective irradiance (E_{eff}).[11] While both types of systems are acceptable, persons performing the measurements should be aware of the differences so that the measurements obtained are appropriately compared with the recommended occupational exposure limits. Equipment used to measure UV radiation should be maintained and calibrated on a regular schedule, as recommended by the manufacturer.

UVGI Safety and Health Program

Employers should consult with persons having expertise in industrial hygiene, engineering, and/or health physics before designing and installing UVGI systems. In addition, the following guidelines should be used to protect workers from overexposure to UV radiation. These guidelines should be incorporated into a UVGI safety and health program. One person should be given responsibility for managing the program.

(1) Exposure Monitoring

a. *Upper Air Irradiation Systems.* Before an upper air UVGI system is activated in the workplace, exposure monitoring should be conducted to determine the levels of UV radiation in the room. The UV radiation levels will be affected by the position of the lamp, fixture design (including presence and position of baffles and louvers), tube type, room dimensions, and presence of UV absorbing or reflecting materials. At a minimum, UV radiation measurements should be made with the detector directly facing the lamp at head or eye height (with maximum levels recorded), to assess the potential UV exposure to the eyes, the most sensitive organ. Because workers typically move around a room or area while performing their duties, it is often not possible to predict how long a worker will be in a given location, nor is it practical to attempt to control exposures administratively by limiting the duration of exposure at a given location. Therefore, the exposure monitoring should be conducted in representative locations to adequately assess the range of potential worker exposures. Worker exposures should be maintained below the NIOSH REL[2] and ACGIH TLV[10] for ultraviolet radiation.

UV radiation measurements should be made: (1) at the time of initial installation of the UVGI system; (2) whenever new tubes are installed; and (3) whenever modifications are made to the UVGI system or to the room that may affect worker exposures (i.e., adjustment of fixture height, location, or position of louvers; addition of UV absorbing or reflecting materials; and changes in room dimensions).

UV radiation measurements may also be obtained to document the UV output of the lamp for tube replacement or other purposes. Because these types of measurements are commonly done close to the source of the UV output, the person obtaining the measurements may be exposed to high levels of UV radiation. UV radiation levels up to 840 $\mu W/cm^2$ (420 μ/cm^2 effective irradiance) have been measured at a distance of four inches from the face of a 30W tube that had been in use several months.[12] Using the NIOSH REL, this exposure level would result in a permissible exposure time of only 7 seconds for workers with unprotected eyes and skin. Because of the high irradiance levels, it would not be practical in this situation to control UV exposures by limiting exposure duration. Skin and eye protection would be needed to protect the worker when making UV measurements close to the source.

b. *Duct Irradiation Systems.* Duct irradiation systems frequently involve the placement of several UV tubes within a section of duct work. Thus, workers who have contact with these lamps are potentially exposed to high levels of UV radiation. This presents a hazard for maintenance workers and others who are responsible for documenting the UV output of these lamps. At one facility where a duct irradiation system was used, UV radiation levels up to 950 $\mu W/cm^2$ were measured at a distance of approximately three feet from a bank of four 39W UV tubes.[11] In this situation, the NIOSH REL would be exceeded in about 6 seconds; therefore, skin and eye protection would be needed to prevent worker overexposures to UV radiation. Most UV exposures resulting from duct irradiation systems can be avoided by inactivating the lamps before maintenance work is done, and providing an access port for viewing the lamps during preventive maintenance inspections. These control measures are discussed further in the Control Methods section of this appendix.

(2) Control Measures

The following control measures should be used to prevent or reduce UV exposures.

a. *Engineering Controls.* 1. In upper air irradiation systems, the UV tubes in the fixture should not be visible from any usual location/position in the room. The fixtures should contain baffles or louvers that are appropriately positioned to direct the UV irradiation to the upper air space. The baffles and louvers should be constructed so that they cannot be easily bent or deformed.

2. In upper air irradiation systems, all highly UV reflecting material should be removed, replaced, or covered. Reflectance values for various materials have been published.[13] Etched aluminum and chromium are examples of materials that have high reflectance values (88 and 45% reflectance, respectively) for 254 nm radiation. Unpainted white wall plaster is reported to have reflectance values of 40–60%.[13]

3. UV-absorbing paints (such as those containing titanium dioxide) can be used on ceilings and walls to minimize reflectance of UV in the occupied space, as needed.

4. The on/off switch for the UVGI lamps should not be located on the same switch as the general room lighting. In addition, these switches should be positioned in such a location that only authorized persons have access to them and they should be locked to ensure that they are not accidentally turned on or off.

5. In duct irradiation systems, there should be an access panel for conducting routine maintenance, monitoring, and cleaning. This access panel should have an interlock or other device to ensure that the tubes are deactivated whenever the panel is opened. To prevent unnecessary UV exposures to maintenance personnel, this port should have a window for viewing the tubes during routine inspections. Ordinary glass (not quartz) and plastics (polycarbonate and polymethylmethacrylate) are sufficient to filter out the UV radiation.[14]

6. All UVGI systems should be inactivated prior to maintenance activity in the affected areas, such as when maintenance workers replace lamps or when entering the upper air space for room maintenance, renovation, or repair work.

b. *Personal Protective Equipment.* UV exposures should be maintained below existing recommended levels. Despite the use of the engineering controls listed above, there may be situations when worker exposures exceed the NIOSH REL, such as when UV measurements are being made close to the lamp source in order to document lamp output, or when maintenance procedures must be performed in areas where UVGI systems are activated. In these and other situations where the NIOSH REL is exceeded, personal protective equipment is needed to prevent worker overexposure to UV radiation. This includes the use of UV-absorbing eyewear with side-shields, head,

neck, and face covering opaque to UV radiation, gloves, and long-sleeved garments. The weave of the fabric has been shown to be the major factor affecting transmission of UV radiation,[15] thus, tightly woven fabrics are recommended. UV-absorbing sunscreens with solar-protection factors of 15 or higher may help protect photosensitive persons.[16]

(3) Labeling

Warning labels should be placed on UV lamp fixtures in upper air irradiation systems and on access panels in duct irradiation systems to alert workers and other room occupants to this potential hazard. These warning labels should be of sufficient size to be visible to room occupants and should be in the appropriate language(s). Examples of warning labels are shown below:

BILLING CODE 4510–26–P

BILLING CODE 4510–26–C

CAUTION
HIGH INTENSITY ULTRAVIOLET ENERGY
PROTECT EYES AND SKIN

CAUTION
HIGH INTENSITY ULTRAVIOLET ENERGY
TURN OFF LAMP BEFORE ENTERING
UPPER ROOM OR DUCT

(4) Training

All workers who have potential exposure to UV radiation from UVGI systems should be receiving training on the hazards, relevant symptoms, and precautions concerning exposure. This training should include specific information on:

a. The rationale for use of UVGI and general principles of operation, including its limitations;

b. Control measures used to prevent or reduce UV radiation exposure;

c. Health effects associated with overexposure to UV radiation (including the potential for additive exposure from other UV sources, such as solar radiation and welding);

d. Recognition of the symptoms of eye and skin damage; and

e. Special precautions to be taken by workers to prevent overexposure to UV radiation (including the use of personal protective equipment).

(5) Medical Recommendations

The worker's medical history should be obtained to determine if the worker suffers from any condition that may be exacerbated by exposure to UV radiation. Workers should be advised that any eye or skin irritation that develops after acute exposure to UV radiation, or any skin lesion that appears on skin repeatedly exposed to UV radiation should be examined by a physician.

(6) Recordkeeping

The employer should maintain accurate and complete records pertaining to the following:

a. Exposure monitoring;

b. Instrument calibration;

c. Documentation of health effects;

d. Training;

e. Maintenance of UVGI systems, including cleaning and replacement of tubes.

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Appendix E to § 1910.1035—Performance Monitoring Procedures for HEPA Filters (Nonmandatory)

This appendix offers nonmandatory guidance on design considerations and performance monitoring of HEPA filters used in air systems that carry air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (e.g., recirculation into building circulating air system, exhausting outdoors near air intakes, etc.).

Both OSHA and CDC recommend against the recirculation of air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* into the general circulating air system of the building or other opportunities where such air may become entrained into the circulating air system (e.g., outdoor exhausting near intakes, transfer to heat wheels, etc.). When recirculation is unavoidable, the air should be cleaned with HEPA filtration. In order to assure effective functioning of these systems, they should be properly designed, installed, and maintained.

Design of HEPA Filtration Systems

The following elements should be considered for incorporation into the design of HEPA filtration systems:

1. Provide upstream prefiltering to reduce dust that may plug the HEPA filter.

2. Provide worker-entry into housings for visual examinations and probe scanning for leaks of filter media and frame-to-filter interfaces. In addition, adequate access should be provided to allow for replacement of the HEPA filters and pre-filters without contaminating the work area by unintentional jarring or dropping of the filters.

3. Provide devices for measuring HEPA filter loading (e.g., pressure differential across a filter).

4. Provide appropriate mounting frames and seals to minimize frame-to-filter leakage.

5. Specify filter media to match operating criteria (e.g., face velocity, volumetric flow rate, pressure drop, etc.).

6. Design upstream and downstream duct to facilitate performance monitoring (e.g., good air mixing for uniform dispersal of challenge aerosols, sectioning to allow isolation of leaks, etc.).

7. HEPA filters must operate in dry airstreams. Tests have shown that exposure

to high humidity for a period of five hours will result in a threefold increase in particle penetration.

Maintenance of HEPA Filtration Systems

HEPA filtration systems are generally passive systems without moving parts, so the majority of filter maintenance activities are associated with performance monitoring. In terms of performance monitoring, HEPA filters are to be monitored for *filter loading* and for possible *leakage* every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness. Leaks in HEPA filters can occur in the following ways: (1) in the filter media, (2) in the bond between media and frame, (3) in the frame gasket, (4) in the support frame, and (5) in between the frame and the wall.

Testing of HEPA filters after installation is used to detect leaks associated with shipping damage and with installation problems such as handling damage, variations in gasket thickness and poorly formed gasket corners.

Periodic testing detects deterioration of components, relaxation of gaskets, clamping devices, weld cracks or other leaks that may develop during use. This deterioration will take place even if the system is not on-line and in use.

Monitoring for Filter Loading

HEPA filtration systems become loaded with particulate matter through use. Although this loading improves particulate arrestance, it eventually increases the pressure drop across the filter assembly. Consequently, the flow capacity begins to diminish and bypass leakage at the frame-to-filter interface increases. Therefore, these filters need to be monitored and changed.

It is imperative that the differential pressures across the HEPA filter remain below the maximum operating resistance level set by the manufacturer and stamped on the filter label. Filter penetration by contaminants can occur when HEPA filters exceed the manufacturer's maximum resistance rating, making the system ineffective.

The operating resistance level is determined by measuring the pressure differential across the filter through use of a pressure sensing device. Measurements of differential pressure across the HEPA filters should be made when the prefilters have been removed. These measurements should be used to predict future HEPA filter replacement or for determining the need for immediate HEPA filter replacement.

Additional control measures can be used to detect a differential pressure that exceeds the maximum operating resistance which signals the alarm's set point (i.e., audible/visual alarms or computerized error messages).

All pressure measurements should be logged and retained in accordance with paragraph (i)(4)(ii) of this standard.

Monitoring for In-service Filter Leakage

In CDC's ''Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities'' [Ex. 4B], the di-octal phthalate (DOP) penetration test as described in Chapter 25 of the *1992 Systems Handbook from the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)* is offered as a method of performance monitoring HEPA filters. The basis of this well-recognized test is to challenge a HEPA filter assembly with a uniformly distributed cloud of 0.3 µm (mass median diameter) DOP aerosol and measure the DOP smoke upstream and downstream with a light-scattering photometer. Penetration ''P'' through the filter assembly is the performance criterion typically specified and is defined as:

$$P = 100\left(\frac{\text{downstream concentration}}{\text{upstream concentration}}\right)\%$$

Penetration is related to filter efficiency ''E'' by the equation:

$$E=100(1-P)\%$$

Therefore, an efficiency of 99.97% is equivalent to P=0.0003.

Other Filter Testing Methods

There are many recognized HEPA filter testing standards. Most of these standards utilize DOP aerosol to challenge the HEPA filters and provide penetration performance data for 0.3 µm size particles. Since TB droplet nuclei range in size from 1 to 5 µm, the DOP aerosol challenge is indicative of droplet nuclei penetration. Some manufacturers may provide bench test data for filtration efficiency versus particle size which may be useful information when selecting filters but may be difficult to duplicate in the field for in-service testing. These test standards include:

1. Standard UL 586, *High-Efficiency, Particulate, Air Filter Units* as published by Underwriters Laboratories, 1990 (Ex. 7–227). This test is designed for bench testing at the factory and does not include the frame-to-filter bypass leakage measured by in-service testing. This test method uses a light beam-photocell combination (photometer) to measure the density of the DOP smoke in the air.

2. Standard ASTM F1471–92, *Air Cleaning Performance of a High-Efficiency Particulate Air-Filter System,* as published by the American Society for Testing and Materials, 1993 (Ex. 7–222). This test can be used in the field for in-service testing of HEPA filters. This test method utilizes a laser aerosol spectrometer which can count particles by particle size.

3. Standard NSF–49, Appendix B, *HEPA Filter Leak Test for Biosafety Cabinets,* as published by the National Sanitation Foundation (Ex. 7–226). This test is designed for in-service HEPA filter testing and utilizes a portable photometer probe which can be passed over the filter frame perimeter to check for bypass leaks.

Unfortunately, there are hazards associated with exposure to DOP. The Material Safety Data Sheet for DOP reports irritation, nausea and numbness as symptoms associated with DOP inhalation. Nausea, diarrhea, reproductive effects, liver enlargement, and cancer are effects associated with ingestion of DOP. Therefore, performance testing that does not utilize DOP should also be considered.

Alternative methods are in use and being developed that capitalize on recently developed optical particle counters (e.g., lasers) that can count particles at specified sizes. For example, the National Environmental Balancing Bureau (NEBB) publishes *Procedural Standards for Certified Testing of Clean rooms'* Section 8.3 presents an *Ambient Particle Aerosol Challenge Method* that utilizes new-generation optical particle counters to measure upstream and downstream concentrations of particles of a specified size (Ex. 7–228). Only ambient air is measured and no aerosol is generated. This method may have merit for TB applications because ambient air has a statistically significant quantity of particles less than 3.0 µm, but at the same time, this high number of particles may overload the instrument.

Because a dark DOP smoke is not required to attenuate light as is the case with a photometer, recently developed optical particle counters offer the opportunity for an alternative non-toxic challenge aerosol like that described in the proposed Standard 52.2 *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* from the American Society of Heating, Refrigerating and Air-Conditioning Engineers. This non-toxic challenge aerosol is based upon potassium chloride (KC) particles which are generated in the 0.3 to 10 µm size range (Ex. 7–224).

Filter Testing Performance Criteria

The following should be considered when setting performance testing criteria: (1) Failure of a HEPA filter in a recirculating air system can have serious consequences; (2) HEPA filters are more efficient in removing droplet nuclei than DOP due to the larger particle size of droplet nuclei; (3) In-service filter penetration testing should match factory testing that is P≤ 0.0003 for 0.3µm challenge particle; (4) The differential pressure drop across a HEPA filter from dirt loading should never exceed the maximum operating resistance set by the manufacturer and stamped on the filter label; (5) Penetration should not exceed 0.0001 when performing localized penetration scanning with a photometer probe around filter frames and across the filter face.

Appendix F to § 1910.1035—A Guide to Writing an Exposure Control Plan (Non-mandatory)

A Guide to Writing an Exposure Control Plan is a non-mandatory appendix developed to assist employers in complying with § 1910.1035 Occupational Exposure to

Tuberculosis. This standard requires employers to have a written Exposure Control Plan (ECP) documenting procedures they use to control exposure to Tuberculosis (TB).

The following guide aids employers in writing the required ECP by reviewing the standard's requirements and providing examples of policy, narrative statements, and a ''fill-in-the-blank'' sample ECP. Before using this guide, employers will need to read the standard. Once familiar with the standard, they can use this appendix to develop a program specific to their facility.

Employers are not required to use the sample ECP included in this guide. They may develop their own format and may include the TB ECP in their overall infection control plan. However, the ECP must include all OSHA required information and all policies and procedures in the plan must be implemented whether the ECP is a separate plan or included in another document. If the TB elements are included in an overall infection control plan, the employer must develop an index referring the reader to their locations within that plan. Since the elements in the sample ECP are the minimum necessary to meet the standard's requirements, employers may enhance the sample with more comprehensive procedures if they wish.

OSHA developed the guide to help employers comply with the standard. The information contained in this Guide to Writing an Exposure Control Plan for Occupational Exposure to Tuberculosis is not considered to be a substitute for the OSH Act or any provisions of the OSHA Standard. It provides general guidance for a particular standards-related topic and should not be considered a legal authority for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

Employers who have additional questions concerning this standard may contact the nearest OSHA office.

How to Use This Guide

A Guide to Writing An Exposure Control Plan has two components: Notes to the Employer and a Sample Exposure Control Plan. Notes to the Employer consists of explanations for some of the standard's ECP requirements, guidance about writing an ECP and information about practices common to a variety of employers. Notes to the Employer is organized to correspond chronologically to the Sample Exposure Control Plan.

The Sample Exposure Control Plan contains examples of policy statements and procedures. It has a number of sections and is organized in program development form. Although it does not always follow the exact sequence of the standard, all elements of the standard are included. Each section of the Sample ECP is cross-referenced to the specific provisions of the standard using the letter and numerical paragraph designation. The Sample ECP has blank spaces to be completed by the employer with site-specific information.

The standard provides a tiered approach to compliance. Not all provisions apply to all facilities. This approach accommodates facilities with varying factors. OSHA's sample ECP accommodates the difference between these types of facilities.

(1) The first tier is employers (other than the operators of a laboratory) that do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have had no cases of confirmed TB in the past 12 months and are located in counties that in the past two years have had zero cases of confirmed infectious TB in one year and fewer than 6 cases of confirmed infectious TB in the other year. Work settings in this tier have presented minimal occupational exposure and therefore may choose to comply with only a limited number of provisions. (See Appendix A). Required elements for these facilities are underlined in the sample ECP. They include: procedures for exposure determination, prompt identification of individuals with suspected or confirmed infectious TB, exposure incident reporting, and procedures for referring individuals with suspected or confirmed TB to facilities with appropriate isolation capabilities.

Employers who wish to have a minimal exposure control plan as described in Appendix A must document the number of cases of tuberculosis reported in their county in the previous twelve month reporting period and the number of individuals with confirmed tuberculosis encountered in the facility in the previous twelve months.

(2) The second tier encompasses employers who use early identification and transfer procedures rather than admit individuals with suspected or confirmed infectious TB. They typically do not have AFB isolation rooms or autopsy rooms or conduct high-hazard procedures in their facility. These facilities can omit the sections about AFB isolation rooms and engineering controls since these provisions do not apply to them unless they have to use temporarily isolate when it is not possible to transfer individuals with suspected or confirmed infectious TB within five hours. Paragraph (c)(2)(ii) lists the requirements of the ECP for this type of facility. In the sample ECP, certain sections are starred (*) to assist facilities that transfer individuals with suspected or confirmed infectious TB within five hours of discovery. These employers may omit the starred sections when writing their ECP.

(3) The third tier covers employers who admit and provide medical services to individuals with suspected or confirmed infectious TB. These employers are required to have AFB isolation rooms and procedures to protect employees working in or around those rooms. In addition, they must have maintenance schedules for engineering controls as well as other protections. Paragraph (c)(2)(iii) lists specific requirements for these facilities. However, if these employers transfer some individuals with suspected or confirmed infectious TB as well as admit and provide medical services for those individuals, the facility must have procedures for the transfer. The sample ECP includes all required ECP elements thus providing guidance to facilities that admit and provide medical services.

Sample Exposure Control Plan Notes to the Employer

Exposure Control Plan (c)(2)

Policies and Program Administration

The standard requires each employer to have a written exposure control plan and to review and update it annually. The Sample Exposure Control Plan has examples of statements reflecting the employer's policy. Blanks are provided for the employer to designate the facility name.

Employers have limited ECP provisions (see Appendix A) if they (1) do not admit or provide medical services to individuals with suspected or confirmed infectious TB, (2) have had no case of confirmed infectious TB in the past 12 months and (3) are 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. (Paragraph (b)). In addition, these employers must determine the number of reported cases in the county for the last twelve month reporting period and record it in the ECP. They must also document the number of confirmed cases of TB in their facilities. The numbers can be recorded in this first section of the ECP.

The written ECP must be accessible to employees, OSHA and NIOSH representatives for viewing and copying as necessary. (Paragraph (c)(2)(vii)) A sample statement regarding the accessibility is written below. OSHA does not require this statement to be written. However, employers may include this type of statement in their ECP to clearly define the company's/organization's policy.

Sample Statement: Employees and/or OSHA or NIOSH representatives may view the ECP at _____ (location of ECP)_____ and may copy the plan as necessary.

Designating a specific person to be responsible for maintaining the exposure control plan is not a requirement of the regulation. However, it is a common practice.

Sample Statement: _____ (responsible person/department) _____ is responsible for maintaining, reviewing and updating the Exposure Control Plan (ECP).

Employee Exposure Determination (Paragraph (c)(1)(i)(A))

In paragraph (c)(1)(i) & (ii), OSHA requires employers to review job classifications in their facilities and determine which employees have occupational exposure to infectious TB (Occupational exposure is defined in paragraph (j) of the standard). All TB exposure determinations must be made without regard to the use of respiratory protection.

There are two basic employee job classifications for employers to consider: (1) jobs in which all employees have occupational exposure to infectious tuberculosis because of the very nature of the job such as respiratory therapists and nurses who work on a pulmonary unit and (2) jobs that result in occupational exposure to tuberculosis when certain tasks or procedures are performed; for example, dietary personnel delivering meals to an individual in AFB isolation or housekeeping staff cleaning an AFB isolation room.

All employees in the first job classification are considered to have occupational exposure to infectious TB, so specific job tasks for this classification are not required to be defined. In the second category, however, only some employees may have occupational exposure and , then, only when performing certain tasks. Therefore, OSHA requires the employer to define those tasks. Examples of tasks in which employees may have occupational exposure to TB include: transporting patients; entering occupied isolation areas to clean or deliver meals; performing maintenance on HVAC systems that exhaust air from occupied AFB isolation rooms; and, performing suctioning and/or aerosolized treatments on patients with suspected/confirmed TB. Tasks may be listed in closely related groups or as individual tasks.

Not all employers have both types of job classifications. Employers are not required to complete both categories unless there are job classifications that pertain to each.

Employee Notification of TB Hazards (Paragraph (c)(2)(i)(B))

The standard requires that the employer include procedures in the ECP ''for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions.''

The employer must assure that employees have enough information to take proper precautions against exposure to TB. However, the employer must also consider the medical confidentiality of the infectious individual and assure that this confidentiality is maintained to the extent possible and consistent with applicable laws.

Employers are expected to define responsibilities and outline procedures used to inform employees of TB hazards. OSHA requires that an employer notify employees by posting signs and labeling ventilation ducts. (Paragraphs (h) (1) & (2))

The following sample statements provide an abbreviated example of some procedures that might be used in a health care facility. These statements are not OSHA requirements but examples.

Sample Statement: As soon as infectious TB is suspected the nurse in charge of the unit must be informed. The nurse in charge of the unit also must assure that (1) the individual is placed in an AFB isolation room marked with a sign: ''No Admittance Without Wearing a Type N95 of More Protective Respirator'', (2) the nursing supervisor and infection control specialist are notified, (3) all staff working on the unit are notified, and (4) proper equipment is obtained.

If the individual with suspected or confirmed infectious TB must be transferred to be placed in an isolation room, all procedures required by this ECP will be utilized, such as masking the individual or if that cannot be done, having the employee don a respirator.

The nurse in charge of the unit immediately notifies the facility engineer to assure that (1) the engineering controls are working properly and (2) all maintenance and contract employees are informed of the potential TB hazard. _____ (maintenance engineer) _____ is to immediately check to assure that all ducts carrying exhaust air from the room occupied by the individual with suspected or confirmed infectious TB are labeled ''Contaminated air—Respiratory Protection Required''.

Dietary, laboratory, and other test order sheets are specially noted to indicate ''Respiratory Isolation—No admittance without an N95 or More Protective Respirator.''

In addition to informing their own employees, host employers are required to notify contractors of TB hazards. Some contractors and contracting employees may be required to enter or work in AFB isolation areas or other areas in the facility where occupational exposure is likely to occur or where air systems may reasonably be anticipated to contain aerosolized *M. tuberculosis.* Since host employers know the location of the hazards, they must inform the contractor. (Paragraph (d)(6))

OSHA requires the employer to post signs at the entrance to (1) rooms or areas used to isolate individuals with suspected or confirmed infectious TB, (2) areas where procedures or services are being performed on an individual with suspected or confirmed infectious tuberculosis and (3) clinical/research laboratories where *M. tuberculosis* is present. (Paragraph (h)(2))

Signs must include a picture of a stop sign, have a red background with white lettering and say: ''No Admittance Without Wearing a N95 or More Protective Respirator.'' The employer may include additional language provided the major message on the sign remains clear. (Paragraph (h)(2)(iii))

After the room is vacated, the sign must remain posted at the entrance until the room or area is ventilated, using the USPHS recommendations for removal efficiency of 99.9%, for the time necessary to permit entry without the use of a respirator. See Appendix C of the standard. (Paragraph (h)(2)(ii))

The room does not need to be ventilated and the sign may be removed immediately if both of the following criteria are met (1) the room was occupied by an individual with suspected infectious tuberculosis and (2) that individual is medically determined to be non-infectious. (Paragraph (h)(2)(ii))

If employers have engineering controls, those controls must be labeled appropriately and the labeling procedures must be noted in the ECP. (Paragraph (h)(1))

The type of HVAC system in the facility will determine where ducts are labeled. Ducts that have HEPA filtration must be labeled at all duct access points located prior to the HEPA filter. HVAC systems that exhaust air directly to the outside must be labeled at all access points, fans and exhaust outlets. (Paragraph (h)(1))

Signs at the entrance to clinical or research laboratories and autopsy suites must include the biohazard symbol, name of the laboratory director or other designated responsible person, *M. tuberculosis*, and special requirements for entering the laboratory or autopsy room. In addition, contaminated laboratory wastes must be labeled with the biohazard symbol or be placed in a red container. (Paragraph (h)(2)(iv))

Although the standard does not require noting this in the ECP, employers may want to document where engineering controls are located in their facility. If an employer chooses to note this, sample verbiage may be:

Sample Statement: _____ (list type of engineering controls in place)

_____

engineering controls are used in the Bronchoscopy suite located on the third floor of this building.

OR

There are no high-hazard procedures performed in this facility. There are no engineering controls in place.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

The employer must investigate circumstances surrounding TB Skin Test conversions and exposure incidents to determine the cause and ways to make changes to prevent similar occurrences. (Paragraph (g)(4)(iv))

The procedures used to report and then to evaluate the incident must be included in this section of the ECP. In addition, employees are required to report incidents to a particular department or person. (Paragraph (c)(2)(i)(C)) This information must be included here, also.

Sample Statement: Exposure incidents are to be reported to _____ (name and department)

. _____

The reporting procedures utilized at __ (organization's name) __ are:

_____

_____

_____

Procedures for evaluating the circumstances surrounding the exposure incident at _____ (organization's name) _____ are:

_____

_____

_____

Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) & (iii)(A))

Each facility is required to establish procedures for promptly identifying individuals with suspected or confirmed infectious TB. The standard considers ''suspected or confirmed infectious TB'' to be:

''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 signs and symptoms of TB; (2) to have a positive acid fast bacilla (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia)''. (Paragraph (j))

This definition must be included in the early identification criteria. Although not mandated by OSHA, some employers add high risk factors like IV drug use,

immunocompromised status, recent immigration from Asia, Africa, Latin America, etc.

Some employers use the *1994 CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* to assist in early identification of TB (Ex. 4). These guidelines state, ''TB is not distributed evenly throughout all segments of the U.S. population'' and defines groups known to have a higher prevalence of TB infection. These high risk groups include ''foreign born persons from Asia, Africa, Latin America and the Caribbean; medically under served populations(e.g. some African-Americans, Hispanics, Asians, and Pacific Islanders, American Indians, and Alaskan Natives); homeless persons; current or former correctional-facility inmates; alcoholics; intravenous drug-users; and the elderly.'' Persons with certain medical conditions have a greater risk of progression from latent infection to active disease. These medical conditions are defined in the 1994 CDC guidelines as: ''HIV infection, silicosis, diabetes mellitus, gastrectomy or jejuno-ileal bypass, being greater than 10% below ideal body weight, chronic renal failure or renal dialysis, immuno-suppression due to drug therapy and some malignancies.''

There are several ways to conduct early identification. Many employers use a questionnaire to quickly assess the individual's health status at intake or admission. Some employers located in communities considered to have a high incidence of TB or working with high risk populations use chest x-rays. Since use of a questionnaire is a common practice, OSHA included one in the Sample ECP. This is not mandatory but is a guide for those employers who may wish to develop a questionnaire.

An example of a policy statement referring to use of a questionnaire is:

Sample Statement: ____ (organization's name) _____ uses the attached questionnaire to assess the individual's health status as related to suspected or confirmed infectious TB. An individual who has two or more of the symptoms of Tuberculosis in addition to a prolonged cough, a positive AFB smear or is known by ____ (organization's name) _____ or any of its employees to be infected with *M. tuberculosis* is categorized as having suspected or confirmed infectious TB.

Employers Who Transfer (Paragraph (c)(2)(ii))

Procedures for Transfer of Individuals With Suspected or Confirmed Tuberculosis

Employers that transfer rather than admit and provide medical services must document their procedures for isolating an individual while awaiting transfer such as segregating and masking the individual and procedures used if the individual cannot be transferred within 5 hours. This includes documenting the type of equipment used (e.g. masks, respirators).

In the remainder of the sample ECP, employers who transfer suspected or confirmed infectious TB within 5 hours of identification may omit starred sections if they do not have isolation rooms and engineering controls.

Employers who do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have not encountered any individuals with confirmed TB in their facility in the past twelve months and who are located in counties that in the past two years have had zero cases of confirmed TB reported in one year and fewer than 6 cases in the other year and wish to claim reduced responsibilities must be prepared to transfer such individuals. Therefore, the standard requires these facilities to have procedures for transferring an individual with suspected or confirmed infectious TB, if encountered. (Appendix A)

Employers Who Admit and Provide Medical Services (Paragraph(c)(2)(iii))

Procedures for Isolating and Managing Care (Paragraph (c)(2)(iii)(B))

The employer must document procedures for isolating individuals with suspected or confirmed infectious TB such as using AFB isolation rooms and procedures for managing care to minimize employee exposure.

Procedures listed in the Sample ECP are limited to the standard requirements. Employers should add any other isolation and segregation procedures used in their facility to assure that their ECP reflects the way they manage isolation and segregation.

Employers who transfer individuals with suspected or confirmed infectious TB do not need to include procedures for isolating and managing care. However, as stated above, they must list procedures for transferring the individual and segregating and masking these individuals while awaiting transfer. In addition, employers who do not perform high hazard procedures in their facilities do not need to notate anything in the high hazard section of the ECP. These employers may wish to enhance their ECP by clarifying their functions, however. A sample of a statement to enhance and clarify is:

Sample Statement: (1) This facility transfers individuals with suspected or confirmed infectious TB within 5 hours of identification, (2) high-hazard procedures are not performed in this facility, (3) there are no engineering controls for TB control at this facility.

Again, the above statements are not OSHA requirements.

Each employer who admits or provides services to individuals with suspected or confirmed infectious TB is required to institute policies and procedures to address the following issues. The procedures in the Sample ECP are an abbreviated version of the OSHA requirements. (Paragraph (c)(2)(iii)(B) (1 through 5)):

- Minimizing the time the suspected/confirmed infectious individual spends outside the AFB isolation room.
- Minimizing the time of employee exposure in AFB isolation rooms or areas by combining as many tasks as possible into one entry.
- Minimizing the number of workers entering AFB isolation rooms.
- Using a properly fitted mask (e.g. surgical mask or valveless respirator) on individuals with suspected or confirmed infectious TB or transporting these individuals in portable containment engineering control when transport or relocation outside of AFB isolation rooms or areas is unavoidable.
- Delaying of elective transport or relocation.
- Providing services in an AFB isolation room or area to the extent feasible (e.g. portable x-ray).
- Assuring that the individual is returned to the isolation room as soon as is practical after the completion of the service or procedure.
- Delaying elective high-hazard procedures or elective surgery until the individual with suspected or confirmed infectious TB is determined to be non-infectious.

Some facilities may have extensive procedures while others may have less involved procedures. The extensiveness of the procedures is determined by the type of tasks and services provided the individual with suspected or confirmed infectious TB in that facility.

Whatever the procedures are, the employer is expected to assure that the procedures comply with the OSHA requirement and that all procedures are implemented.

*High-Hazard Procedures (Paragraph (c)(2)(iii)(C))

The ECP must contain a list of high-hazard procedures performed in the facility.

(*)All high-hazard procedures that may aerosolize *M. tuberculosis* must be performed in an AFB isolation room, an AFB isolation area, or in a special AFB containment booth. Examples of high hazard procedures include bronchoscopy, pulmonary function testing, endoscopy and autopsy on an individual with suspected or confirmed infectious TB.

*Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

Employers who have engineering controls in any part of their facility must include a maintenance and performance monitoring schedule in this section of the ECP. (Appendix E)

Sample Statement: Engineering controls for infectious TB are inspected, maintained and undergo performance monitoring according to the following schedule:

_____

_____

_____

Clinical and Research Laboratory Biosafety Procedures Paragraph (c)(2)(iv))

OSHA requires that the facility's laboratory director determine and document the biosafety level at which the laboratory operates.

In addition, the laboratory director must determine and document the need for (1) controlled access, (2) anterooms, (3) sealed windows, (4) directional airflow, (5) preventing recirculation of laboratory exhaust air, (6) filtration of exhaust air before discharge to the outside and (7) thimble exhaust connections for biological safety cabinets.

The laboratory director must consult and follow the guidelines found in the OSHA regulation.

Home Health Care or Home-Based Hospice Care (Paragraph (c)(2)(v))

OSHA requires employers of Home Care or Home-based Hospice care to include procedures for prompt identification of individuals with suspected or confirmed infectious TB. In addition procedures to minimize employee exposure to such individuals and a list of any high-hazard procedures performed in the home and procedures for delaying elective high hazards procedures or surgery until the individual is non-infectious must be included in the ECP.

Sample Exposure Control Plan

Exposure Control Plan (Paragraph(c)(2))

Policies and Program Administration

*(company name) maintains, reviews and updates the Exposure Control Plan (ECP) at least annually, and whenever necessary to reflect new or modified tasks, procedures and engineering controls * that affect occupational exposure. The ECP is also updated to reflect new or revised employee positions with occupational exposure.*

This facility has had _____ cases of confirmed TB in the last 12 months. (Paragraph (c)(2)(vi))

(b) This facility is located in _____ county which has reported cases of TB in the last twelve month reporting period.

Employee Exposure Determination (Paragraph (c)(2)(i)(A))

ALL employees in the following job classifications have or may have occupational exposure to TB (Paragraph(c)(1)(i)(A)): JOB TITLE

_____

_____

_____

Employees in the following job classifications have or may have exposure to TB when they are performing the listed tasks and procedures (Paragraph (c)(1)(B)):

JOB TITLE	TASKS/PROCEDURES

Employee Notification of TB Hazard (Paragraph (c)(2)(i)(B))

(organization's name) uses the following procedures to assure that all employees with job tasks that offer potential for occupational exposure are informed of the hazard and take proper precautions against exposure to TB.

(procedures described)

_____

(*) _____ (responsible person(s)/ department) _____ maintains contact with all outside contractors who provide temporary or contract employees who may incur occupational exposure. This allows the contractor to institute precautions to protect his or her employees. Theses contractors are informed of the TB hazard and the facility's procedures for protecting themselves from exposure.

(*) Signs are posted at the entrance to:

(*) 1) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB,

(*) 2) Areas where procedures or services are being performed on an individual with suspected/confirmed infectious TB, and

(*) 3) clinical land research laboratories where M. tuberculosis is present.

(*) All signs are red with white text stating ''No Admittance Without a Type N95 of More Protective Respirator'' and have a picture of a stop sign. (See attached sample).

(*) _____ (organization's name) _____ ensures that warning labels are placed on AFB isolation room exhaust ducts and areas where occupational exposure to TB is expected.

(*) All systems carrying air that may be contain aerosolized M. Tuberculosis are labeled at all points where ducts are accessed prior to HEPA filter, at fans and at the discharge outlets of non-HEPA filtered direct discharge systems. The label says: ''Contaminated Air—Respiratory Protection Required''.

(*) ____ (organization's name) ____ notifies employees entering the laboratory and the autopsy room of the occupational hazards by using signs at the entrance to both these locations. These signs indicate the name and telephone number of the director of the laboratory, infectious agent—*M. tuberculosis,* and the special requirements for entering the laboratory or autopsy room. The sign displays the Biohazard symbol.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

All employees must report exposure incidents immediately to (responsible person(s)/department). ____ (Organization's name) is responsible for investigating, evaluating, and documenting the circumstances surrounding the exposure incident for instituting changes to prevent similar occurrences.

The following procedures are used to investigate/evaluate exposure incidents at (organization's name):

_____

_____

_____

Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) and (iii)(A))

(Organization's name) considers an individual to be suspected of having Infectious TB (unless the individual's condition has been medically determined to result from a cause other than TB) if either the company or any of its employees determine(s)/learn(s)that the individual:

- *has a persistent cough lasting 3 or more weeks with 2 or more signs and symptoms of active infectious TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia),*
- *has a positive AFB smear,*

Based on the criteria listed above, (Organization's name) utilizes the following procedures for early detection of individuals with suspected/confirmed infectious TB.

_____

_____

_____

Employers Who Transfer (Paragraph(c)(2)(ii))

Procedures for Transfer of Individuals With Suspected or Confirmed Infectious TB:

If/when an isolation room is not available at our facility, the individual is transferred within 5 hours of identifying the infectivity to a facility (name of facility) where isolation rooms are available. The following procedures for transfer of an individual with suspected/confirmed infectious tuberculosis are utilized:

_____

_____

_____

While awaiting transfer, the individual is masked or segregated to protect employees who are without respiratory protection. (organization's name) uses the following procedures/equipment when masking and segregating an individual with suspected/ confirmed infectious TB:

_____

_____

If a situation arises and the individual is not able to be transferred within 5 hours of identifying the suspected or confirmed infectious TB, the following procedures, including AFB isolation, are instituted: (list procedures used)

_____

_____

_____

Employers Who Admit and Provide Medical Services (Paragraph (c)(2)(iii))

Procedures to Isolate and Manage Care (Paragraph(c)(2)(iii)(B))

(*) The following procedures are used to isolate individuals with suspected or confirmed infectious TB.

(*) All individuals with suspected or confirmed infectious TB are placed in AFB isolation rooms or areas.

(*) _____ (organization's name) _____ uses the following procedures to minimize the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area: _____ (detail responsibilities and steps)

_____

_____

(Paragraph(C)(2)(iii)(B)(1))

(*) Employee exposure in AFB isolation rooms is minimized by combining tasks the amount of time an employee spends in an AFB isolation room is minimized by _____ (list procedures used)

_____

_____ (Paragraph (c)(2)(iii)(B)(2))

(*) ____ (organization's name) _____ uses the following procedures, minimizing the number of workers entering AFB isolation rooms:

_____

_____

(*) ____ (organization's name) _____ utilizes the following procedures to delay

transport or relocation within the facility until the individual is considered non-infectious:

_____

_____

_____

(Paragraph (c)(2)(iii)(B)(3))

(*) Services are provided in the patient's room whenever feasible such as portable x-ray and _____ (list other services provided in the patient's room to minimize exposure)

_____

_____

_____

(*) This facility uses _____ (list the type of engineering controls in use—properly fitted masks or valveless respirators for the for the patient to be masked or portable containment devices)

_____

on individuals with suspected or confirmed infectious TB when it is necessary to transport or relocate the individual.

(Paragraph (c)(2)(iii)(B)(4))

(*) The following procedures assure that the individual is returned to the AFB isolation room as soon as practical after completion of the procedure _____ (list of procedures)

_____

_____

_____

(*) Services that cannot be rendered in the patient's room are provided in and area that meets the requirements for an AFB isolation room.

(*) Elective high-hazard procedures and surgery are delayed until the patient is non-infectious.(Paragraph(c)(2)(iii)(B)(5))

(*) HIGH-HAZARD PROCEDURES (Paragraph(c)(2)(iii)(C))

(*) High-hazard procedures (where TB may be aerosolized) require special precautions to prevent/minimize occupational exposure to infectious TB. The following high-hazard procedures are performed at this facility: _____ (list procedures)

_____

_____

_____

(*) Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

(*) The maintenance schedule for engineering controls is as follows:

(*) Daily—Negative pressure areas are qualitatively demonstrated by using smoke trails.

(*) Whenever HEPA filters are changed, the system is inspected and its performance monitored in accordance with current USPHS guidelines. HEPA filters are changed every _____ in this facility or whenever

_____

_____

_____

(*) Every six months—HEPA filters in contained air exhaust systems are inspected, maintained and performance monitored in accordance with current USPHS guidelines.

Clinical and/or Research Laboratories (Paragraph (c)(2)(iv))

The _____ (type of laboratory—clinical or research) _____ operates at biosafety level _____ as determined by _____ (name of laboratory director) _____ for _____ (organization's name) _____. This is in accordance with CDC/NIOSH Biosafety in Microbiological and Biomedical Laboratories).

The following controls are in operation in the laboratory at this facility _____ (list controlled access, anterooms, sealed windows and other controls required in the standard and determined necessary by the laboratory director)

_____

_____

_____

(c)(2)(v) HOME HEALTH CARE OR HOME-BASED HOSPICE

See the following sections of this sample ECP for information regarding the ECP requirements:

(1) (c)(2)(ii) & (iii)(A) for sample statements regarding the Prompt identification of individuals with suspected or confirmed infectious TB.

(2) (c)(2)(iii) for sample statements re: procedures for minimizing employee exposure.

(3) (c)(2)(iii)(C) for a sample statement regarding high hazard procedures.

The procedures in this Exposure Control Plan minimize the occupational exposure to TB. The procedures for isolating and managing care are used until the individual with suspected or confirmed infectious TB is determined to be non-infectious or until the diagnosis for TB is ruled out.

Evaluation

Early Detection of Tuberculosis

This questionnaire gives guidance in identifying individuals who meet OSHA's definition of ''suspected infectious tuberculosis'' so that appropriate controls can be initiated.

The questionnaire has two parts: (1) reviewing the individual's TB history and (2) assessing current symptoms.

INSTRUCTIONS:

- Record each answer with a check mark
- Add your comments as the evaluator at the bottom of the page.
- Institute the facility's exposure control measures outlined in the facility's Exposure Control Plan, Respiratory Protection and Medical Surveillance Program and refer the individual for further evaluation if the individual has:

(1) A persistent cough lasting 3 or more weeks and two or more symptoms of active TB.

(2) Had a positive TB test on mucous that he/she coughed up.

(3) Been told that he/she had TB and was treated, but never finished the medication.

TB HISTORY
(Part One)

Have you ever had a positive TB skin test?
Yes No Don't Know

Have you ever had an abnormal chest x-ray?
Yes No Don't Know
If yes, how long ago?

Have you recently had the mucous you cough up tested for TB?
Yes No Don't Know
If yes, were you told it was positive
Yes No Don't Know

Have you ever been told you have Infectious Tuberculous?
Yes No Don't Know
If yes, how long ago?

Have you ever been treated with medication for Infectious TB?
Yes No Don't Know
If yes, how many medications?
One Two Over Two
Are you still taking TB medicine?
Yes No
Did you take all the TB medicine until the health care professional told you that you were finished?
Yes No

Do you live with or have you been in close contact with someone who was recently diagnosed with TB? (e.g. shelter roommate, close friend, relative)
Yes No Don't Know

CURRENT SYMPTOMS
(Part Two)

Do you have a cough that has lasted longer than three weeks?
Yes No

Do you cough up blood or mucous?
Yes No

Have you lost your appetite? Aren't hungry?
Yes No

Have you lost weight (more than 10 pounds) in the last two months? without trying to?
Yes No

Do you have night sweats (need to change the sheets or your clothes because they are wet)?
Yes No

Evaluator Comments:

_____

_____

_____

Exposure Control Methods Implemented?
Yes No

Referred for Further Evaluation? Yes No

_____

Evaluator's Signature

_____

Date

Appendix G to § 1910.1035—Smoke-trail Testing Method for Negative Pressure Isolation Rooms or Areas

A. Test Method Description

The purpose of a negative pressure AFB isolation room or area is to prevent TB droplet nuclei from escaping the isolation room or area and entering adjacent or surrounding spaces (e.g., a corridor). One method to check for negative room pressure is to use smoke-trails to demonstrate that the pressure differential is inducing airflow from the corridor through the crack at the bottom of the door (undercut) and into the isolation room or area. When performing a smoke-trail test, follow these recommendations where applicable:

1. Test only with the isolation room or area door shut. If not equipped with an anteroom, it is assumed that there will be a loss of space pressure control when the isolation or area door is opened and closed. It is not necessary to demonstrate direction of airflow when the door is open.

2. If there is an anteroom, release smoke at the inner door undercut, with both anteroom doors shut.

3. In addition to a pedestrian entry, some isolation rooms or areas are also accessed through a wider wheeled-bed stretcher door. Release smoke at all door entrances to isolation rooms or areas.

4. So that the individual conducting the test does not advertently force the smoke into the isolation room or area, hold the smoke bottle/tube parallel to the door so the smoke is released perpendicular to the direction of airflow through the door undercut.

5. Position the smoke bottle/tube tight to the floor, centered in the middle of the door jamb and approximately two inches out in front of the door.

6. Release a puff of smoke and observe the resulting direction of airflow. Repeat the test at least once or until consistent results are obtained.

7. Minimize momentum imparted to the smoke by squeezing the bulb or bottle slowly. This will also help minimize the volume of smoke released.

8. Depending on the velocity of the air through the door undercut, the smoke plume will stay disorganized or it will form a distinct streamline. In either case, the smoke will directionally behave in one of three ways. It will:

(a) Go through the door undercut into the isolation room or area,

(b) Remain motionless, or

(c) Be blown back into the corridor.

Negative pressure requires that the smoke be drawn into the isolation room or area through the door undercut.

9. Release smoke from the corridor side of the door only for occupied AFB isolation rooms or areas. If the room is unoccupied, also release smoke inside the isolation room or area (same position as in Step No. 5) to verify that released smoke remains contained in the isolation room or area (i.e., the smoke serves as a surrogate for TB droplet nuclei).

10. To assist in observing the smoke when photography or videotaping is performed, it is recommended that a dark surface be placed on the floor to maximize the contrast. Be aware that most autofocusing cameras cannot focus on smoke.

B. Testing ''As Used'' Conditions

Testing of negative pressure AFB isolation rooms or areas requires that the test reflect as-used conditions. As-used means that the isolation room or area shall remain the same during testing conditions as it is when in use for isolation. Consider the following use variables that may affect space pressurization and the performance of the negative pressure AFB isolation room or area:

1. Patient toilet rooms are mechanically exhausted to control odors. The position of the toilet room door may affect the pressure differential between the isolation room or area and the corridor. Smoke-trail tests should be performed both with the toilet room door open and the toilet room door closed. This will not be necessary if the toilet room door is normally closed and controlled to that position by a mechanical door closer.

2. An open window will adversely affect the performance of a negative pressure AFB isolation room or area. If the isolation room or area is equipped with an operable window, perform smoke-trail tests with the window open and the window closed.

3. There may be corridor doors that isolate the respiratory ward or wing from the rest of the facility. These corridor doors are provided in the initial design to facilitate space pressurization schemes and/or building life safety codes. Leaving the corridor doors open to the rest of the facility may cause pressure changes in the corridor (e.g., proximity to an elevator lobby) and affect the performance of the negative pressure AFB isolation room or area. Perform isolation room or area smoke-trail testing with these corridor doors in their ''as-used'' position, which is either normally open or normally closed.

4. Isolation rooms or areas may be equipped with auxiliary, fan-powered, recirculating, stand alone HEPA filtration or UV units. These units must be running when smoke-trail tests are performed.

5. Do not restrict corridor foot traffic while performing smoke-trail tests.

6. Negative pressure is accomplished by exhausting more air than is supplied to the isolation room or area. Some HVAC systems employ variable air volume (VAV) supply air and sometimes VAV exhaust air. By varying the supply air delivered to the space to satisfy thermal requirements, these VAV systems can adversely impact the performance of a negative pressure isolation room. If the isolation room or area or the corridor is served by a VAV system, the smoke test should be performed twice. Perform the smoke test with the thermostat set at the desired temperature and again with the thermostat set at a lower or higher temperature, depending upon the season, thus simulating the full volumetric flowrate range of the VAV system serving the area being tested.

C. Smoke

Most smoke tubes, bottles and sticks use titanium chloride ($TiCl_4$) to produce a visible fume. There is no OSHA PEL or ACGIH TLV for this chemical, although it is a recognized inhalation irritant. Health care professionals may be concerned about releasing $TiCl_4$ around pulmonary patients. The smoke released at the door undercut makes only one pass through the isolation room and is exhausted directly outside. (Isolation room air is typically not ''recirculated.'')

The CDC in the supplementary information to the 1994 TB Guidelines has indicated that ''The concern over the use of smoke is unfounded.''(Ex. 4B) Controlled tests by NIOSH have shown that the quantity of smoke released during the test is so minute that it is not measurable in the air. Nonirritating smoke tubes are available and may be utilized.

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