Federal Register

Friday
October 17, 1997

# Part II

# Department of Labor

## Occupational Safety and Health Administration

## 29 CFR Part 1910

## Occupational Exposure to Tuberculosis; Proposed Rule

**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.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**

I. Introduction
II. Pertinent Legal Authority
III. Events Leading to the Proposed Standard
IV. Health Effects
V. Preliminary Risk Assessment
VI. Significance of Risk
VII. Preliminary Economic and Regulatory Flexibility Analysis
VIII. Unfunded Mandates
IX. Environmental Impact
X. Summary and Explanation of the Proposed Standard
XI. Public Participation—Notice of Hearing
XII. Authority and Signature
XIII. The Proposed Standard

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<br>• 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<br>• 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<br>• 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<br>• 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).<br>• 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).<br>• 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).<br>• 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).<br>• 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).<br>• 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).<br>• 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).<br>• 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).<br>• 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:<br>• Enter an AFB isolation room or area<br>• Perform or are present during the performance of high-hazard procedures<br>• Transport or are present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle<br>• 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).<br>• 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.<br>• 1 hour for employees with occupational exposure who are not assigned respirators<br>• 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: .....<br>2 hours for employees required to wear respirators<br>1 hour for employees with occupational exposure who are not assigned respirators<br>½ hours for employees required to wear respirators<br>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:.<br>1 hour for employees required to wear respirators<br>½ hour for employees with occupational exposure who are not assigned respirators<br>• For 75% of exposed employees able to demonstrate competence<br>• 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.

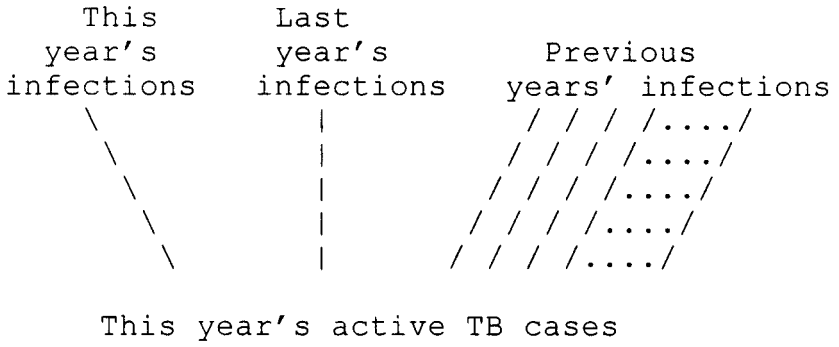
3. Estimation of Background Risk of TB Infection

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




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.

BILLING CODE 4510–26–P

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 |

BILLING CODE 4510–26–C

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