Background

Since 1985, the incidence of tuberculosis (TB) in the general U.S. population has increased approximately 14 percent, reversing a 30-year downward trend. In 1993, 25,313 new cases of TB were reported in the United States. Increases in the incidence of TB have been observed in some geographic areas. These increases are related partially to the high risk for TB among immunosuppressed persons, particularly those infected with human immunodeficiency virus (HIV). Foreign-born persons from high prevalence areas (such as Asia, Africa, and Latin America) also constitute high risk groups for TB. Foreign-born persons (as a group) residing in the United States have higher rates of tuberculosis than persons born in the United States. In 1989, the overall U.S. tuberculosis rate was 9.5 per 100,000. In the period 1986-1989, approximately 22% of all reported cases of tuberculosis occurred in the foreign-born population. A majority of foreign-born persons who develop tuberculosis do so within the first five years after they enter the United States.

Other factors (e.g., socioeconomic) have also contributed to the increases. Outbreaks have occurred in hospitals, correctional institutions, homeless shelters, nursing homes, and residential care facilities for AIDS patients. Since 1994 and 1995, there has been a decrease in the number of TB cases in the United States. This is likely due to increased awareness and efforts in the prevention and control of TB, including the implementation of TB control measures recommended by the CDC and required by OSHA.

Recently, drug resistant strains of *M. tuberculosis* have become a serious concern and cases of multi-drug-resistant (MDR) TB have occurred in 40 states. In a recent New York City study, 33% of cases had organisms resistant to the two most effective drugs available for treating the disease. When organisms are resistant to both drugs, the course of the treatment is expected to increase from six months to 18-24 months, and the cure rate could decrease from 100% to 60% or less.

In 1995, approximately 425 cases of TB were reported in Michigan, which reflected a TB rate of 5.0 per 100,000 population. Approximately 66% of the reported cases resided in Macomb, Oakland, and Wayne counties.
In a 1992 American Hospital Association CDC survey, 12% of the respondents reported nosocomial TB transmission to health care workers. More than 80% of those facilities noted TB skin test conversions among workers. More than 100 cases of active TB disease in health care workers were known to CDC, and reported to Congress by Dr. William Roper in the Spring of 1993. Twelve (12) health care workers have died. Nationwide, at least several hundred employees have become infected and required medical treatment after workplace exposure to TB. In general, persons who become infected with TB have approximately a 10% risk for developing active TB in their lifetimes.

*M. tuberculosis* is carried through the air in tiny infectious droplet nuclei of 1 to 5 microns in diameter. These droplets may be generated when a person with pulmonary and laryngeal TB disease coughs, speaks, sings, sneezes, spits. When inhaled by susceptible persons, the mycobacteria in these droplets may become established in the lungs and, in some cases, spread throughout the body. After an interval of months, years, or even decades, the initial infection may then progress to clinical illness (i.e., tuberculosis disease). Transmission of TB is most likely to occur from persons with pulmonary or laryngeal TB that are not on effective anti-TB therapy and who have not been placed in respiratory isolation.

In occupational health care settings, where patients with TB are seen, workers in close contact with persons who have infectious TB are at increased risk of infection with TB. Certain high-risk medical procedures that are cough-inducing or aerosol generating can further increase the risk of infection in health care workers.

The employer's obligations are those set forth in the Michigan Occupational Safety and Health Act of 1974. Recommendations for preventing the transmission of TB for health care settings were originally established in the 1990 CDC Guidelines. In October of 1994, those guidelines were revised and published in the Morbidity and Mortality Weekly Report, October 28, 1994, Vol. 43/No. RR-13. The new guidelines emphasize the control of TB through an effective TB infection control program. Under these guidelines, the control of TB is to be accomplished through early identification, isolation and treatment of persons with infectious TB, use of engineering and administrative procedures to reduce the risk of exposure, and through the use of respiratory protection. MIOSHA believes that these guidelines reflect an appropriate, widely recognized and accepted standard practice to be followed by employers in carrying out their responsibilities under Act 154 in Michigan.

SCOPE AND COVERAGE OF MIOSHA DIRECTIVE 96-9

Enforcement of MIOSHA TB directive 96-9 covers only those workplaces where the CDC has identified workers as having a greater risk and/or incidence of TB infection than the general population. These workplaces are as follows:

1. health care facilities
2. correctional institutions
3. long-term care facilities for the elderly
4. homeless shelters
5. drug treatment centers

Note: Health care facilities include hospitals where patients with confirmed or suspected TB are treated, or to which they are transported. Coverage of non-hospital health care settings (i.e., doctors' offices, home-health care providers, local public health facilities, clinics, etc.) includes only those personnel who would be present during the performance of high hazard procedures on suspect or active TB patients. Dental health care personnel are covered by this directive only if they perform dental treatment on suspect or active TB patients. Emergency Medical Services personnel (while performing high hazard procedures on a known or suspect TB individual, or transporting suspect or confirmed infectious TB individuals in a closed vehicle) and law enforcement officers (while working with known or suspected TB detainees in jail cells) are also covered under this directive.

Homeless shelters - Due to a variety of circumstances, the control of TB in homeless shelters present unique problems for the protection of workers. Shelters must establish protocols that provide for rapid early identification followed by immediate transfer of suspect or confirmed cases if the shelters have elected not to treat these patients in-house.

Local public health department employees who have reasonable anticipation of work-related contact with individuals who are suspected or confirmed to have infectious TB, or employees who have exposure to TB contaminated air are considered to have occupational TB exposure. These exposed employees need to have TB Training and annual Mantoux skin testing. These employees should also be provided adequate respiratory protection during prolonged exposure to infectious TB patients.

Employee exposure determination should be based on the following exposure scenarios:

a. Potential exposure to the exhaled air from an individual with suspected or confirmed pulmonary TB disease.

b. Exposure, without protection, to a high hazard procedure performed on an individual with suspected or confirmed infectious TB disease, and which has the potential to generate infectious airborne droplet nuclei.
Note: Examples of high hazard procedures include aerosolized medication treatment, bronchoscopy, sputum induction, endotracheal intubation and suctioning procedures, emergency dental endoscopic procedures, and autopsies.

A suspected TB case is one in which the facility has identified an individual as having symptoms consistent with TB. The CDC has identified the symptoms to be: productive cough, coughing up blood, weight loss, loss of appetite, lethargy/weakness, night sweats, or fever.

COMPLIANCE REQUIREMENTS

An employer, whose employees work in any of the five designated workplaces and have a TB exposure scenario as defined above, are required to implement a TB exposure control program for employee TB protection. The plan or program should include an infection control program, respiratory protection, employee training, skin testing, medical surveillance, engineering/administrative controls, and recordkeeping. Although the program does not necessarily have to be in writing, a written program is recommended. The required TB exposure control program must address the following:

A. Early Identification of Patients/ Clients

The employer is required to implement a protocol for the early identification of individuals with active tuberculosis. The employer is also required to conduct a TB risk assessment of its facility at least yearly. Each covered facility may establish its own criteria for early identification of suspect TB incidents.

B. Medical Surveillance

Initial TB Skin Testing

The employer, in covered workplaces, must offer TB mantoux skin tests (at no cost to the employees) to all current potentially exposed employees, and to all new employees within 10 days of hire and prior to occupational exposure. A two-step baseline shall be used for all new employees who exhibit initial negative PPD skin test results, but had not had any previously documented negative TB skin test results during the preceding 12 months. All TB skin tests, as well as post-exposure follow-up and treatment evaluations must be offered at no cost to the employees, and at times and locations convenient to the employees. The reading and interpretation of the TB skin test must be performed by a qualified individual as described in the CDC Guidelines.

Periodic TB Skin Testing

Mantoux skin testing must be conducted every three (3) months for workers who work in areas where there are clusters of workers with PPD conversions or evidence of person-to-
person transmission with no clear identification of the source of the transmission, or workers who had unprotected exposure within the past year; every six (6) months for workers who perform high hazard procedures on known or suspected infectious TB individuals; annually for workers who have direct contact with, or provide direct care to known or suspected TB patients.

Workers with documented positive TB skin test results who have received treatment for the disease, or preventive therapy for infection, are exempt from the TB skin test, but must be periodically informed about the symptoms of TB and the need for immediate evaluation, by a physician or trained health care provider, to determine if symptoms of TB disease have developed.

C. Reassessment Following Exposure or Change in Health

Workers who experience exposure to individuals who have suspected or confirmed TB, and for whom infection control precautions have not been taken, shall be managed in accordance with CDC recommendations and as outlined in section D below. Employees who develop symptoms of TB disease shall be immediately evaluated according to the CDC Guidelines.

D. Case Management of Infected Employees

Covered employers are required to perform evaluation and case management of infected workers (at no cost to employees) as follows:

Conversion to a positive mantoux skin test must be followed-up promptly by appropriate physical, laboratory, and radiographic evaluations to determine whether the employee has infectious TB disease.

Any employee who exhibits symptoms of active TB (e.g., weight loss, night sweats, bloody sputum, anorexia, or fever), must be evaluated promptly for TB. The employee should not be allowed to return to work until a diagnosis of TB has been excluded, or until the employee is on therapy and has been determined by a physician to be noninfectious.

Covered employers are required to make reasonable accommodations (e.g., alternative job assignments or voluntary transfer) for employees who are known to be HIV-infected or otherwise severely immunosuppressed, and who work in settings where they may be exposed to M. tuberculosis. Such employees must be referred to employee health professionals who can individually counsel the employees regarding their risk for TB. Upon the request of the immunocompromised employee, the employer must offer, but not compel, a work setting in which the employee would have the lowest possible risk for occupational exposure to M. tuberculosis. Evaluation of these situations should also include consideration of the provisions of the Americans With Disabilities Act of 1990 and other applicable federal, state, and local laws.
E. **Worker Education and Training**

The employer is required to provide for all affected current and new employees (upon hire), training and information to ensure employee knowledge of such issues as the mode of TB transmission, signs, and symptoms of TB disease, TB skin testing, medical surveillance and therapy, and site specific infection control protocols including the purpose and proper use of control methods (e.g., isolation rooms, ventilation, respiratory protection, etc.). Training should be repeated as needed.

Workers must be trained to recognize and report to a designated person(s), any patient(s) or client(s) with symptoms suggestive of infectious TB, and shall also be instructed on the post exposure protocols to be followed in the event of an employee exposure incident.

F. **Engineering Controls**

Individuals with suspected or confirmed infectious TB disease must be placed in respiratory acid-fast bacilli (AFB) isolation rooms. High hazard procedures on individuals with suspected or confirmed infectious TB disease must be performed in AFB treatment or isolation rooms, booths, and/or hoods. AFB isolation refers to a negative pressure room or an area that exhausts room air directly outside or through HEPA filters if recirculation is unavoidable.

Facilities which intend to transfer suspected or known TB individuals to another facility for treatment and therapy, do not need to establish AFB isolation rooms. Other measures (such as administrative controls, respiratory protection, training and information, etc.) must however be used to protect employees from exposure to TB.

Isolation and treatment rooms in use by individuals with suspected or confirmed infectious TB disease must be maintained under negative pressure to induce airflow into the room from all surrounding areas (e.g., corridors, ceiling plenums, plumbing, plumbing chases, etc).

**Note:** At a minimum, the employer must use non-irritating smoke trails or some other indicator to periodically ascertain that direction of airflow is from the corridor into the isolation or treatment room with the door closed. Such demonstration must be conducted at least monthly for rooms that could be used for TB patients, and daily for rooms occupied by suspect or confirmed TB patients. If an anteroom exists, direction of airflow must be demonstrated at the inner door between the isolation/treatment room and the anteroom.

The opening and closing of entrance door into an occupied TB isolation or treatment room (which does not have an anteroom) compromises the ability to maintain negative pressure in the room. For such rooms, the employer must utilize a combination of controls and practices to minimize spillage of contaminated air into the corridor or surrounding areas (e.g. minimizing entry into the room, adjusting the hydraulic closer to slow the door movement and reduce air
displacement effects, adjusting doors to swing into the room where fire codes permit, avoiding placement of room exhaust intake near the door, using telephones or intercom to communicate with patients, etc).

Air exhausted from AFB isolation or treatment rooms must be safely exhausted directly outdoors, and not recirculated into the general ventilation system.

In circumstances where recirculation is unavoidable, HEPA filters must be installed in the duct system from the room to the general ventilation system. For these HEPA filters, a regularly scheduled monitoring program to demonstrate as-installed effectiveness should be instituted.

The air handling system must be appropriately marked with a TB warning sign in locations where maintenance personnel would have access into the ductwork, fans, or filters for maintenance or repair activities.

In order to avoid leakage, all potentially contaminated air which is ducted through the facility from TB isolation or treatment rooms must be kept under negative pressure until it is discharged safely outdoors (i.e., away from occupied areas and air intakes), or decontaminated by a recognized process (e.g., HEPA filter) before being recirculated back into the building. HEPA filters must be properly installed and maintained. Use of UV radiation, as a sole means of decontamination is NOT acceptable. The CDC Guidelines allow the use of the UV radiation in waiting rooms, emergency rooms, and corridors where patients with undiagnosed TB could potentially contaminate the air.

If high-hazard procedures are performed in AFB isolation or treatment rooms without the use of source control ventilation or local exhaust ventilation (e.g., hood, booth, tent, etc.) and droplets are released into the environment (e.g., through coughing), then a purge time interval must be imposed during which personnel must use a respirator when entering the room. Nonessential personnel and individuals must be restricted from entering the room during the purge time interval.

Interim or supplemental ventilation units equipped with HEPA filters are acceptable.

G. Respiratory Protection

NIOSH has determined that the minimal acceptable respirator for protection against TB infection is the N-95 air purifying, particulate respirator certified under 42 CFR Part 84, Subpart K. HEPA, N-99, or N-100 respirators are also acceptable.

Affected employees must wear the appropriate respirators as indicated above in the following circumstances:
a. When the employees enter rooms housing individuals with suspected or confirmed infectious TB.

b. When employees enter an AFB isolation room after discharge of TB patient, and before the room has been properly purged.

c. When the employees are present during the performance of high hazard procedures on individuals who have suspected or confirmed infectious TB.

d. When emergency medical response personnel or others transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.

When respiratory protection (including disposable respirators) are required, a complete respiratory protection program must be in place in accordance with Rule 3502(2). Employees who are required to wear respirators must be trained on how to use and maintain the respirators.

If an employer chooses to use disposable respirators as part of their respiratory protection program, their reuse by the same health care worker is permitted as long as the respirators maintain their structural and functional integrity, and the filter materials are not physically damaged or soiled. The facility must address the circumstances in which a disposable respirator will be considered to be contaminated and not available for reuse.

H. Access to Employee Medical and Exposure Record:

A record concerning employee exposure to TB is considered an employee exposure record in accordance with MIOSHA Rules.

A record of TB skin test results, as well as records of employee medical evaluation and treatment, are considered employee medical records. A worker's TB exposure record should contain a notation indicating the type of "TB" to which the employee was exposed (e.g., multi-drug resistant TB) if known.

I. Accident Prevention Signs and Tags

A warning sign must be posted outside each occupied respiratory AFB isolation or treatment room. The sign must contain a signal word (i.e., "STOP", "HALT", "NO ADMITTANCE") or a biological hazard symbol, as well as a major message (e.g., "special respiratory isolation", "respiratory isolation", or "AFB isolation"). A description of the necessary precautions to be taken (e.g., "respirators must be donned before entering") or a message referring visitors to the nursing station for pre-entry instructions must also be posted outside the room.
Biological hazard tags or signs must be posted or attached on air handling components (e.g., fans, ducts, filters) that transport TB contaminated air so as to alert maintenance personnel who work on the air handling systems of the TB hazards.

J. Recording/Reporting Requirements

For employers who are covered by the TB directive, TB infection (positive TB Mantoux skin test) and TB disease are both recordable on the MIOSHA 200 log. All such entries must be made in column 7(c) of the log. Positive TB skin test results from pre-employment screening or baseline skin testing, administered within the first two weeks of employment and prior to any potential workplace exposure to TB, do not have to be recorded on MIOSHA 200 log.

If an employee's TB infection (which has been entered on the MIOSHA 200 log) progresses to TB disease during the required five year record retention period for the MIOSHA 200 log, the original entry for the infection shall be updated to reflect the new information. Because it is clinically difficult to determine if TB disease resulted from an earlier or subsequent exposure, only one case should be entered to avoid double counting.

In accordance with part 56 of Public Act 368 of 1978, employers or their representing physicians are required to submit to the Division of Occupational Health reports of known or suspected occupational TB infection or disease.