OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR — Occupational Safety and Health Administration

DIRECTIVE NUMBER: CPL 02-02-078	EFFECTIVE DATE: 06/30/2015

SUBJECT: Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis

ABSTRACT

Purpose: This Instruction provides general enforcement policies and procedures to be followed when conducting inspections and issuing citations related to occupational exposure to tuberculosis (TB).

Scope: This Instruction applies OSHA-wide.

References: Centers for Disease Control and Prevention (CDC), *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005*, MMWR December 30, 2005/ Vol. 54/ No. RR-17.

OSHA Instruction CPL 02-00-150, *Field Operations Manual (FOM)*, April 22, 2011.

OSHA Instruction CPL 02-00-158, *Inspection Procedures for the Respiratory Protection Standard*, June 26, 2014.

OSHA Instruction CPL 02-00-135, *Recordkeeping Policies and Procedures Manual*, December 30, 2004.

Cancellations: OSHA Instruction CPL 02-00-106, *Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis*, February 9, 1996.

State Impact: Notice of intent and equivalency is required. See section VII.

Action Offices: National, Regional and Area Offices, and Consultation Project Offices.

Originating Office: Directorate of Enforcement Programs.

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By and Under the Authority of

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Executive Summary

This Instruction supersedes CPL 02-00-106, *Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis* (February 9, 1996), which reflected guidance from a 1994 report of the Centers for Disease Control and Prevention (CDC), "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities (1994)." This Instruction reflects guidance from the updated CDC report: "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005."

And this Instruction provides information concerning OSHA's general enforcement policy and procedures for conducting inspections and issuing citations related to occupational tuberculosis (TB) hazards.

Significant Changes

This Instruction explicitly covers additional workplaces regarded as healthcare settings, e.g., settings in which emergency medical services are provided, and laboratories handling clinical specimens that may contain *M. tuberculosis*.

This Instruction uses the term "tuberculin skin test" (TST) instead of "purified protein derivative test" (PPD). This Instruction also introduces a newer screening method: the blood analysis for *M. tuberculosis* (BAMT).

This Instruction uses the following risk classifications for healthcare settings: low, medium, and potential ongoing transmission. Also, in some scenarios this Instruction calls for less frequent TB screening for workers.

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I. **Purpose**.

This Instruction provides general enforcement policy and procedures to be followed when conducting inspections and issuing citations related to occupational exposure to *M. tuberculosis* (TB).

II. **Scope**.

This Instruction applies OSHA-wide.

III. **Cancellations**.

This instruction cancels OSHA Instruction CPL 02-00-106, *Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis* (February 9, 1996).

IV. **Significant Changes**.

This Instruction supersedes CPL 02-00-106, dated February 9, 1996, and includes the following changes:

A. This Instruction explicitly covers additional workplaces regarded as healthcare settings, e.g., settings in which emergency medical services are provided, and laboratories handling clinical specimens that may contain *Mycobacterium tuberculosis.*

B. This Instruction uses the term "tuberculin skin test" (TST) instead of "purified protein derivative test" (PPD). This Instruction also introduces a newer screening method: the blood analysis for *M. tuberculosis* (BAMT).

C. This Instruction uses the following risk classifications for healthcare settings: low, medium, and potential ongoing transmission. Also, in some scenarios this Instruction calls for less frequent TB screening for workers.

V. **References**.

A. 29 CFR Part 1904, Recording and Reporting Occupational Injuries and Illnesses.

B. 29 CFR Part 1910, Occupational Safety and Health Standards.

C. ADM 04-00-001, *OSHA Safety and Health Management System*, May 23, 2011.

D. CPL 02-00-158, *Inspection Procedures for the Respiratory Protection Standard*, June 26, 2014.

E. CPL 02-00-135, *Recordkeeping Policies and Procedures Manual*, December 30, 2004.

F. CPL 02-00-150, *Field Operations Manual* (FOM), April 22, 2011.

G. CPL 02-01-050, *Enforcement Guidance for Personal Protective Equipment in General Industry*, February 10, 2011

H. CPL 02-02-054, *Respiratory Protection Program Guidelines*, July 14, 2000.

I. CPL 02-02-072, *Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records*, August 22, 2007.

J. Centers for Disease Control and Prevention (CDC): "*Biosafety in Microbiological and Biomedical Laboratories*" 5th Edition (December 2009).

K. CDC Morbidity and Mortality Weekly Report (MMWR): *Guidelines for Using the QuantiFERON®-TB GOLD Test for Detecting Mycobacterium tuberculosis Infection, United States*, December 16, 2005/Vol. 54/No. RR-15.

L. CDC MMWR: *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, with Special Focus on HIV-Related Issues*, December 7, 1990/Vol. 39/No. RR-17.

M. CDC MMWR: *Guidelines for Infection Control in Dental Health- Care Settings -- 2003*, December 19, 2003/Vol. 52/No.RR-17.

N. CDC MMWR: *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005*, December 30, 2005/Vol. 54/No. RR-17.

O. CDC MMWR: *Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC*, July 7, 2006/Vol. 55/No. RR-9.

P. Executive Order 12196 (February 26, 1980)--Occupational safety and health programs for Federal employees.

Q. PER 04-00-005, *OSHA Medical Examination Program*, August 22, 2009.

R. Section 5(a)(1) of the Occupational Safety and Health Act of 1970 (General Duty Clause) and 29 CFR 1960.8(a).

VI. **Expiration Date**.

This Instruction will remain in effect until canceled or superseded by an instruction or notice.

VII. **Federal Program Change**.

This Instruction establishes agency enforcement policies and procedures to be followed when conducting inspections and issuing citations related to occupational exposure to TB in healthcare settings.

A. **Federal Agencies**. This Instruction describes a change that may affect federal agencies and shall be followed when conducting inspections in federal agency settings. It is the responsibility of the head of each federal agency to establish and maintain an effective and comprehensive safety and health program. 29 U.S.C. § 668(a). Executive Order 12196, Section 1-201, and 29 CFR 1960.16 generally require federal agencies to comply with OSHA standards.

B. **State Plan States.** A Notice of Intent and Equivalency is required. States with OSHA-approved State Plans must have their own inspection policies and procedures related to occupational exposure to TB. The State Plans' policies and procedures must be at least as effective as those described in this Instruction and must be available for review.

State Plans are required to notify OSHA within 60 days whether they intend to adopt policies and procedures identical to this Instruction or to adopt or maintain different policies and procedures for conducting inspections and issuing citations related to occupational exposure to TB. If a State Plan adopts or maintains policies and procedures that differ from those of Federal OSHA, the state must identify the differences and either post its policies and procedures on its State Plan website and provide the link to OSHA or provide an electronic copy of its policies and procedures to OSHA along with information on how the public may obtain a copy from the state. If a State Plan adopts policies and procedures identical to those adopted by Federal OSHA, the State Plan must provide the date of adoption to OSHA. State Plans must adopt identical or equally effective policies and procedures within 6 months, and post or submit the necessary documentation within 60 days of adoption. OSHA will provide summary information on the state responses to this Instruction on its website at www.osha.gov/dcsp/osp/index.html.

VIII. **Action Offices**.

A. **Responsible Office**. Directorate of Enforcement Programs, Office of

Health Enforcement.

B. **Action Offices**. National, Regional, and Area Offices; State Plan States, and Consultation Project Offices.

C. **Information Offices**. OSHA National Offices.

IX. **Actions Required**.

OSHA Regional Administrators and Area Directors should use the guidelines in this Instruction to ensure that uniform inspection procedures and guidelines are followed by compliance safety and health officers (CSHOs). Prior to conducting inspections of healthcare settings, CSHOs are encouraged to consult with the regional TB coordinators.

X. **Application**.

This Instruction applies OSHA-wide to all interventions, inspections, and violation abatement assistance. This Instruction also applies to OSHA outreach efforts that include compliance assistance, and cooperative programs, training and education. This Instruction applies to all On-Site Consultation Projects. Regardless of whether the worksite is under federal or state jurisdiction, 21(d) and 23(g) funded State Consultation Projects are required to prioritize and schedule On-Site Consultation Services to private-sector employers.

XI. **Background**.

Since 1953, with the cooperation of state and local health departments, the CDC has collected information on newly-reported cases of TB in the United States. According to the CDC, a resurgence of TB in the mid-1980s was marked by several years of increasing case counts. The number of reported TB cases peaked in 1992. Case counts began decreasing again in 1993, and 2013 marked the twenty-first year of decline in the total number of TB cases reported in the United States since the peak of the resurgence. In total, 9,582 TB cases were reported in the United States in 2013, and approximately 4% of those cases were among healthcare workers (CDC Fact Sheet, *Trends in Tuberculosis*, 2013). This represents a rate of 3.0 cases per 100,000 persons, the lowest recorded rate since national reporting began in 1953.

Despite the decreasing TB case rate, however, greater progress should be made. Additionally, multi-drug-resistant (MDR) tuberculosis and extremely drug-resistant (XDR) tuberculosis continue to pose serious threats to workers in healthcare settings. OSHA will continue to enforce employers' obligations to protect affected employees against the hazards associated with TB.

M. tuberculosis is carried through the air in tiny (i.e., 1 to 5 microns in diameter) infectious particles called droplet nuclei. These droplet nuclei may be generated when a person with pulmonary or laryngeal TB disease coughs, sneezes, shouts, or sings. When inhaled by susceptible persons, the mycobacteria in these droplet nuclei may become established in the lungs and spread throughout the body. Most individuals infected with TB do not show symptoms; however, five to ten percent of those infected, and who are not treated for latent TB infection (LTBI), will develop TB disease within their lifetimes. Progression from initial infection to clinical illness (i.e., TB disease manifesting signs or symptoms) may occur after an interval of months, or even years, with the risk being highest during the first several years after infection. Transmission of TB is most likely to occur from persons with pulmonary or laryngeal TB who are not on an effective anti-TB therapy and who have not been placed in respiratory isolation.

In healthcare settings where patients with TB receive care, workers exposed to TB droplet nuclei are at increased risk of TB infection. Conducting cough-inducing or aerosol-generating procedures on persons with suspected or confirmed infectious TB disease can further increase the risk of infection in workers.

In 1990, the CDC adopted guidelines for preventing the transmission of TB in healthcare settings. In October of 1994, the CDC revised those guidelines, emphasizing the control of TB through an effective TB infection control program. The guidelines were updated again in December of 2005 to reflect shifts in the incidence and distribution of, and control methods for, TB, and changes in prevailing healthcare practices. See 2005 CDC Guidelines, p. 2.

The following are some of the significant differences between the 1994 and 2005 CDC guidelines (2005 CDC Guidelines, pp. 2-3):

A. The risk assessment process in the 2005 Guidelines calls for the assessment of additional aspects of infection control procedures.

B. The 2005 Guidelines introduce new terminology. For example, the term "tuberculin skin test" (TST) replaces the term "purified protein derivative test" (PPD).

C. The whole-blood interferon gamma release assay (IGRA), QuantiFERON®-TB Gold test (QFT-G) (Cellestis Limited, Carnegie, Victoria, Australia), is a Food and Drug Administration (FDA)-approved in vitro cytokine-based assay for cell-mediated immune reactivity to *M. tuberculosis*. Under the 2005 Guidelines, it may be used instead of a TST in TB screening programs. IGRA is an example of a blood assay for *M. tuberculosis* (BAMT).

D. The 2005 Guidelines decrease the frequency of TB screening for workers in some settings, and change the criteria for determining screening frequency.

E. The 2005 Guidelines cover an expanded group of healthcare settings; covered settings include laboratories, dental clinics, and additional outpatient and nontraditional facility-based settings.

F. The 2005 Guidelines usually apply to an entire healthcare setting rather than to individual areas within a setting.

G. The 2005 Guidelines use the word "setting" instead of "facility" to expand the scope of covered locations.

XII. **Inspection Scheduling and Scope**.

A. For purposes of this Instruction, "healthcare setting" is defined as "any setting in which healthcare is delivered and workers might share air space with persons with TB disease or come in contact with clinical TB specimens."

B. In workplaces containing healthcare settings, Area Offices shall conduct inspections related to occupational exposure to TB in the following circumstances:

1. In response to any valid employee complaint regarding TB exposure or in response to any valid referral regarding TB exposure from a government agency or safety and health professional.

   NOTE: Complaints received from state and local government employees who are outside federal jurisdiction in federal enforcement states must be referred to the appropriate agency by the Area Office.

2. In response to TB-related employee fatalities or catastrophes.

3. As part of all health inspections in facilities where the incidence of TB infection among patients/clients in the relevant facility or healthcare setting is greater than the incidence of TB among individuals in the most local general population for which the health department has information.

C. The following are examples of healthcare settings that may be inspected in accordance with this Instruction. Various types of healthcare settings might be present in a single facility.

1. Inpatient settings may include: Patient rooms, emergency departments, intensive care units, surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation/respiratory therapy rooms, autopsy suites, and embalming rooms.

2. Outpatient settings may include: TB treatment facilities, medical offices, ambulatory-care settings, dialysis units, and dental-care settings.

3. Nontraditional facility-based settings may include: Emergency medical service (EMS) facilities, medical settings in correctional facilities (e.g., prisons, jails, and detention centers), long-term care settings (e.g., hospices and skilled nursing facilities), drug treatment centers, and homeless shelters.

D. Home Healthcare: TB inspections of employers with employees who work in home healthcare settings should be limited to employer program evaluations and off-site employee interviews.

XIII. **Inspection Procedures**.

This section outlines procedures for conducting inspections and issuing citations for hazards associated with occupational exposure to TB. In addition, CSHOs shall follow the general inspection procedures in CPL 02-00-150, *Field Operations Manual (FOM)* (April 22, 2011), Chapter 3. CSHOs shall also consult other OSHA directives, appendices, and other references cited in this Instruction for further guidance as needed.

A. All inspections related to occupational exposure to TB should include a review of the employer's written plans for employee TB protection. Such plans may include a TB infection control program, a respiratory protection plan, and a medical screening program. Employee interviews and site observations are also an integral part of the evaluation process.

B. Healthcare facilities generally have infection control programs (covering both patients and workers) and employee health programs. Management of these functions may be performed by a team or by an individual. Upon entry, the CSHO should request the presence of the infection control director and the occupational health professional responsible for the control of occupational health hazard(s). Other individuals who may be responsible for providing records pertinent to the inspection include: the training director, the facility engineer, and the director of nursing.

C. The CSHO must determine whether the facility has had a suspected or confirmed TB case among patients/clients or employees within the six

months prior to the opening conference. This determination may be based, in part, upon interviews and a review of available infection control data. As soon as possible after an inspection has been initiated, the CSHO should contact the appropriate local or state health department to determine whether the facility has reported any TB cases during the previous year. The CSHO shall also review OSHA 300 log entries for confirmed cases of work-related TB. If the CSHO determines there are no suspected or confirmed TB cases among patients/clients or employees in the facility within the previous six months, he or she should suspend the TB portion of the inspection.

D. If the facility has had a suspected or confirmed TB case within the previous six months, the CSHO shall proceed with the TB portion of the inspection. The CSHO should verify implementation of the employer's plans for TB protection through employee interviews and direct observations where feasible. Professional judgment should be used to identify which settings in the facility should be inspected during the walkthrough (e.g., patient rooms, emergency departments, radiology departments, intensive care units, surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation/respiratory therapy rooms, autopsy suites, and embalming rooms). Compliance will be determined through review of the facility plans for employee TB protection, employee interviews, and an inspection of appropriate areas of the facility.

E. CSHOs who perform smoke-tube testing of ventilation systems in isolation rooms should review the protocol in the 2005 CDC Guidelines (p. 65, Figure 5), and should adhere to the procedures described in Appendix B of this Instruction. **Smoke testing should not be conducted in occupied rooms unless it can be determined that there is no potential respiratory impact on the patient**. CSHOs must be prepared to present the employer with the safety data sheet (SDS) for the smoke that is released during a smoke-tube test.

F. CSHOs should consult with the Office of Occupational Medicine (OOM) for technical/medical support as needed, including when accessing and analyzing employee medical records and other health information (see section XVI.E, *Access to Employee Exposure and Medical Records*, of this Instruction), obtaining a Medical Access Order, and consulting with physicians and other healthcare professionals.

XIV. **Compliance Officer Protection**.

A. Area Directors or Assistant Area Directors must ensure that CSHOs performing TB-related inspections are familiar with the 2005 CDC Guidelines and the terminology used in the Guidelines and are adequately

trained (through either course work or field/work experience in healthcare settings). Consultation with the regional TB coordinators is encouraged prior to beginning such inspections.

B. CSHOs should exercise professional judgment and extreme caution when engaging in activities that may involve potential exposure to TB. A CSHO can assess hazards and the adequacy of his or her planned inspection practices by asking the employer if there are any facility-imposed exposure control requirements that he or she will need to adhere to during the inspection and by interviewing employees. CSHOs must observe all facility-imposed requirements designed to prevent exposure.

C. CSHOs generally should not enter occupied airborne infection isolation rooms (AIIRs) to evaluate compliance. If a CSHO must enter a recently vacated AIIR, sufficient time should pass to allow the room's airflow to adequately purge the room before he or she enters. (For information on clearance rates, see 2005 CDC Guidelines, p. 20, Table 1.) Prior to entering an occupied AIIR, or a recently vacated AIIR that has not been adequately purged, a CSHO must discuss the need for entry with the Area Director.

D. If the CSHO, in consultation with the Area Director, determines that it is necessary to enter an occupied AIIR, or a recently-vacated AIIR that has not been adequately purged, (e.g., in order to perform air tests), he or she must comply with facility-imposed PPE requirements and this Instruction, and proceed as directed following consultation with his or her supervisor. At a minimum, the CSHO must wear a half-mask negative pressure respirator with at least N95-rated filters.

E. OSHA Instruction PER 04-00-005, *OSHA Medical Examination Program (OMEP)* (August 22, 2009), requires new hires to have 2-step TSTs as part of their pre-placement examinations. A TST is offered annually to CSHOs who have reported a work-related exposure to active TB. A TST can be obtained between periodic examinations at the request of management. If a CSHO is exposed to any individual(s) with active TB disease, he or she can have a TST 8 to 10 weeks after the exposure is thought to have occurred. OOM should be contacted for authorization and for any other questions concerning TB exposure and the Medical Examination Program. Federal Occupational Health (FOH) can provide a TST once it is authorized by OOM. FOH will refer CSHOs with positive TSTs to the local health department or other appropriate facility for evaluation.

F. CSHOs must, at a minimum, wash their hands with soap and water after each inspection related to occupational TB hazards. If handwashing facilities are not immediately available, CSHOs must use hand sanitizers or antiseptic towelettes.

G. Where practical, photographs, or videotaping shall be used for case documentation. Under no circumstances will CSHOs photograph or videotape patients. CSHOs must take all necessary precautions to assure and protect patient confidentiality.

XV. **Citation Policy**.

CSHOs shall follow relevant chapters of the FOM and this Instruction when preparing and issuing citations or notices for violations related to TB. The following requirements may apply to TB hazards found in healthcare settings. Employers must comply with applicable provisions of these requirements when TB hazards are present:

A. Section 5(a)(1) of the OSH Act – General Duty Clause (and 29 CFR 1960.8(a) for federal facilities);

B. 29 CFR 1910.134 – Respiratory Protection;

C. 29 CFR 1910.145 – Specifications for Accident Prevention Signs and Tags;

D. 29 CFR 1910.1020 – Access to Employee Exposure and Medical Records;

E. 29 CFR Part 1904 – Recording and Reporting Occupational Injuries and Illnesses;

F. 29 CFR 1910.132 - General Requirements for Personal Protective Equipment.

XVI. **Violations**.

If an employer does not comply with the requirements of the OSH Act or applicable OSHA standards, the Area Director should consider appropriate citations or notices. Although citations are to be classified on a case-by-case basis, the violations described below will often be classified as serious because occupational exposure to TB hazards can result in a substantial probability of death or serious physical harm.

A. **General Duty Clause:**

Section 5(a)(1) of the OSH Act provides, "Each employer . . . shall 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." And 29 CFR 1960.8(a)

similarly provides: "The head of each [federal] agency shall furnish to each employee 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."

The 2005 CDC Guidelines can be used to show industry recognition of the hazards associated with occupational exposure to TB. The Guidelines also contain widely accepted standards of practice employers can follow in carrying out their responsibilities under the OSH Act.

1. Because OSHA's standards do not completely address the hazards associated with occupational exposure to TB, employers may have obligations under the General Duty Clause (Section 5(a)(1)) or 29 CFR 1960.8(a) to take further measures to protect workers from those hazards. In appropriate cases, the Area Director, in consultation with the Regional Office of the Solicitor and the OSHA Regional and National Offices, should consider issuing a 5(a)(1) citation, or a notice under 1960.8(a), to an employer that has employees working in healthcare settings who have been exposed to the following, without adequate protection. within the prior 6 months:

    a) The exhaled air of an individual with suspected or confirmed pulmonary TB disease; or

        NOTE: A suspected case is one in which healthcare providers are considering a diagnosis of TB. The CDC has identified the symptoms of TB to include: coughing for 3 weeks or longer, coughing up blood, hoarseness, unexplained weight loss, loss of appetite, fatigue, night sweats, fever, and chest pain. The CDC has also noted that whether providers suspect TB may depend on the geographic area and the population being served. See 2005 CDC Guidelines, p. 16. The following populations may be at higher risk for exposure to and infection with TB: close contacts of individuals with pulmonary TB disease; foreign-born persons; residents and employees of congregate settings such as correctional facilities, long-term-care facilities and homeless shelters; and medically underserved and low income populations. See 2005 CDC Guidelines, pp. 4-5.

    b) Cough-inducing or aerosol-generating procedures performed on an individual with suspected or confirmed TB disease that have the potential to generate infectious airborne droplet nuclei.

NOTE: Examples of cough-inducing or aerosol-generating procedures include aerosolized medication treatment, bronchoscopy, sputum induction, endotracheal intubation and extubation, suctioning procedures, dental procedures, endoscopic procedures, and autopsies. See 2005 CDC Guidelines, p. 40.

2. When conducting TB-related inspections, CSHOs should evaluate whether the employer has implemented appropriate abatement measures. An employer's failure to implement feasible abatement measures should be considered when evaluating whether to issue a 5(a)(1) citation or notice under 1960.8(a). Deficiencies found in any of the categories identified in paragraphs XVI.A.2(a)-(f) below, can result in a serious hazard that may be the basis for a citation under 5(a)(1) or a notice under 29 CFR 1960.8(a).

   a) TB Infection Control Program.

      The CDC recommends that employers develop written TB infection control plans that outline a protocol for the early identification of individuals with suspected or confirmed TB. The plan should be updated annually. The program should be supervised by appropriate personnel, e.g., a person or group with expertise in LTBI, TB disease, infection control, occupational health, environmental controls, and respiratory protection. See 2005 CDC Guidelines, pp. 8-9.

   b) TB Risk Assessment

      The CDC recommends that employers conduct initial and ongoing evaluations of the risk for TB transmission regardless of whether patients with suspected or confirmed TB disease are expected to be encountered in the setting. See 2005 CDC Guidelines, p. 9. The three TB screening risk classifications are low risk, medium risk, and potential ongoing transmission. See 2005 CDC Guidelines, p. 10.

      The classification of low risk should apply to settings in which workers are not expected to encounter persons with TB or clinical specimens that might contain *M. tuberculosis*. The classification of medium risk should apply to settings in which workers will or will possibly be exposed to persons with TB disease or to clinical specimens that might contain *M. tuberculosis*. The "potential ongoing transmission" classification should

apply temporarily to any setting where there is evidence suggestive of person-to-person (e.g., patient-to-patient, patient-to-worker, worker-to-patient, or worker-to-worker) transmission of *M. tuberculosis* during the preceding year. See 2005 CDC Guidelines, p. 10.

The types of administrative, environmental, and respiratory protection controls needed, and the need for medical surveillance, will depend on the risk classification assigned to the setting as a result of the risk assessment. Risk assessments also serve as on-going evaluation tools for TB infection control programs. See 2005 CDC Guidelines, pp. 9-10 and Appendix B – *TB Risk Assessment Worksheet*.

NOTE: If the facility has not completed a risk assessment, the Area Director should consider citing the employer for a failure to "identify and evaluate the respiratory hazard(s) in the workplace" (29 CFR 1910.134(d)(1)(iii)) or for a failure to "assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment" (29 CFR 1910.132(d)(1)). See also paragraphs XVI.B and XVI.C, below.

c) Medical Surveillance.

The 2005 CDC Guidelines recommend that TB screening programs cover workers who perform any of the following activities: a) entering patient or treatment rooms used for suspected or confirmed TB cases (whether or not a patient is present); b) participating in cough-inducing or aerosol-generating procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medication); c) participating in M. tuberculosis specimen processing (whether suspected or confirmed); or d) installing, maintaining, or replacing environmental controls in areas in which one encounters persons with TB disease. See 2005 CDC Guidelines, p. 4. The CDC has compiled a list of specific workers who might be included in a TB surveillance program (2005 CDC Guidelines, pp. 3-4).

Initial Exams. The CDC generally recommends that employers offer a baseline BAMT or TST to all new workers in healthcare settings (2005 CDC Guidelines, p. 28).

NOTE: A "TB skin test," or TST, means the intradermal injection (Mantoux Method) of PPD (a tuberculin antigen) with subsequent measurement of the indurations (hardened mass) by designated, trained personnel.

A two-step baseline TST should be used for new employees who have not had a documented negative TST result during the preceding 12 months (2005 CDC Guidelines, Box 1, p. 29). Alternatively, the BAMT can be used (2005 CDC Guidelines, p. 28). With the BAMT, only a single test is required to establish the baseline (2005 CDC Guidelines, p.29). TB tests should be offered at no cost, and at times and locations that are convenient for, employees.

NOTE: A positive result to the second step (but not the first step) of a baseline two-step TST is probably caused by boosting, not by recent infection with M. tuberculosis. Such responses can result from remote infections with M. tuberculosis or previous Bacille Calmette-Guérin (BCG) vaccination. Two-step testing minimizes the likelihood that boosting will lead to an unwarranted suspicion of M. tuberculosis transmission based on subsequent testing. See 2005 CDC Guidelines, p. 28. The BAMT may be preferable for testing employees who have previously been provided the BCG vaccine, as it is not expected to result in false-positive results. See 2005 CDC Guidelines, p. 29.

NOTE: The reading and interpretation of TB skin tests should be performed by qualified individuals in the manner described in the 2005 CDC Guidelines (p. 46*).*

Periodic Evaluations. CSHOs should determine whether TB testing has been conducted in accord with Appendix C of the 2005 CDC Guidelines for employees in low risk settings, medium risk settings, and settings with the potential for ongoing transmission. The employer's decisions concerning medical surveillance should be based on up-to-date risk assessments. See 2005 CDC Guidelines, p. 30.

In low risk settings, annual screening is not necessary; however, if an exposure to a person with, or specimen containing, TB occurs, the employer should provide screening and update the risk assessment in accord with the 2005 CDC Guidelines.

In medium risk settings, screening should be provided at least every year.

In settings where there is the potential for ongoing transmission, workers should be tested every 8 – 10 weeks until a determination is made that there is no more ongoing transmission. At that point, the setting should be reclassified as medium risk, and should remain at that classification (at a minimum) for at least one year.

Serial testing is not necessary if an employee has (1) a documented history of TB disease; (2) a documented positive test result; or (3) documented completion of treatment for LTBI or TB disease (2005 CDC Guidelines, p. 29). Persons with positive TST or BAMT results should receive one baseline chest radiograph to exclude a diagnosis of TB disease. Further chest radiographs are not needed unless the patient has symptoms or signs of TB disease or unless ordered by a physician for a specific diagnostic examination. Instead of participating in serial skin testing, workers with positive TST results should receive a medical evaluation and a symptom screen. The frequency of this medical evaluation should be determined by the risk assessment for the setting. See 2005 CDC Guidelines, p. 80.

Staggered serial follow-up screening (e.g., not testing all employees in the same department in the same month) increases the chances that infection-control problems will be detected early (2005 CDC Guidelines, p. 30).

d) Case Management of Infected Employees:

Evaluation of Potentially Infected Employees. The CDC recommends that a worker with a newly recognized positive TST or BAMT, a TST conversion, or signs or symptoms of TB disease be evaluated promptly to determine whether he or she has infectious TB disease (2005 CDC Guidelines, pp. 30-31).

Work Restrictions for Infectious Employees. A worker with confirmed infectious pulmonary, laryngeal, endobroncheal, or tracheal TB disease or a draining TB skin lesion should be excluded from the workplace. He or she should not be allowed to return to work until:

1) He or she provides three consecutive negative sputum samples collected in 8 to 24-hour intervals (including at least one sample taken in the early morning);

2) He or she has responded to anti-tuberculosis treatment that will probably be effective; and

3) A physician knowledgeable and experienced in managing TB disease has determined that he or she is noninfectious. See 2005 CDC Guidelines, p. 31.

Workers with extra-pulmonary TB disease usually do not need to be excluded from work as long as the disease does not affect the respiratory tract (2005 CDC Guidelines, p. 31).

Workers with LTBI can work. If they do not complete a full course of treatment for LTBI, they should be counseled about the risk for developing TB disease and instructed to report TB symptoms immediately. See 2005 CDC Guidelines, p. 31.

e) Employee Education and Training**.**

The CDC recommends that employers ensure that workers receive TB training relevant to their work. Training should emphasize the risks posed by undiagnosed individuals with TB disease and the measures that can be taken to reduce the risk. Training should be documented and repeated as needed. See 2005 CDC Guidelines, pp. 27-28.

The CDC website provides guidance regarding appropriate content for TB training programs and materials. See http://www.cdc.gov/tb and http://www.findtbresources.org.

f) Engineering Controls.

CSHOs should evaluate whether employers have implemented appropriate engineering controls. The following are some controls recommended by the 2005 CDC Guidelines. See the 2005 Guidelines for more complete information about engineering controls that can be used to protect workers from occupational exposure to TB. CSHOs may consult the Salt Lake Technical Center (SLTC) for assistance in evaluating the adequacy of control

measures.

Patients with suspected or confirmed infectious TB disease should be isolated in an AIIR (2005 CDC Guidelines, p. 17). Cough-inducing or aerosol-generating procedures performed on patients with diagnosed infectious TB disease should be done in an AIIR or with the use of local exhaust ventilation (2005 CDC Guidelines, pp. 22-23).

An AIIR is a single-occupancy negative pressure patient-care room or enclosure (see definition of AIIR in Appendix A of this Instruction). The air from an AIIR should be exhausted directly to the outside of the building or, if recirculation of that air is unavoidable, passed through a high efficiency particulate air (HEPA) filter (2005 CDC Guidelines, pp. 66-67). (A HEPA filter is a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter.) HEPA filters should be installed in the duct system exiting the room to remove infectious organisms from the air before it returns to the general ventilation system (2005 CDC Guidelines, p. 67). The employer should implement a scheduled maintenance program for HEPA filters that includes procedures for installing, removing, and disposing of filter elements (2005 CDC Guidelines, p. 69).

NOTE: Maintenance on HEPA filters should be performed only by adequately trained and protected personnel and only while the ventilation system or room-air recirculation unit is off. Employees performing maintenance and replacing filters on ventilation systems that are potentially contaminated with M. tuberculosis should wear appropriate respiratory protection in addition to eye and hand protection. When feasible, HEPA filters can be disinfected in a 10% bleach solution or in another appropriate mycobacteriacide before removal. In addition, filter housing should be labeled with appropriate warnings. Filters and other potentially contaminated materials should be disposed of in accordance with applicable local or state regulations. Pre-filters should be handled and disposed in the same manner as HEPA filters. See 2005 CDC Guidelines, p. 69.

Ultraviolet germicidal irradiation (UVGI) may be effective in killing or inactivating TB. It should not be used as the sole means of decontamination, however. UVGI is not a

substitute for HEPA filtration. It may be used as a supplement or adjunct to other TB infection-control and ventilation measures. The CDC Guidelines note the use of UVGI in waiting rooms, shelters, and other places where people with undiagnosed TB could potentially contaminate the air. See 2005 CDC Guidelines, pp. 69-70.

In circumstances where air from an AIIR must be recirculated back into the room (e.g., where there is no general ventilation system), recirculation may be achieved by either fixed or portable room-air recirculation systems. Fixed recirculation systems are preferred to portable (freestanding) units because they can be installed with a higher degree of reliability and can have a higher airflow capacity than portable systems. Also, fixed systems reduce the potential for the short-circuiting of air as the distance between the air intake and exhaust is greater. See 2005 CDC Guidelines, pp. 67-69.

AIIRs should be kept under negative pressure to induce airflow into the room or enclosure from all surrounding areas. Negative pressure must be monitored to ensure that air is always flowing from the corridor (or surrounding area) into the AIIR. The negative pressure should be ≥ 0.01 inches of water gauge. See 2005 CDC Guidelines, pp. 63-65.

NOTE: Negative pressure can be monitored using non-irritating smoke trails or other indicators to demonstrate that the direction of airflow is from the corridor or adjacent area into the AIIR. Pressure indicating equipment, such as continuous positive and negative pressure monitors, air velocity indicators, and alarms can be installed on an AIIR to verify proper room pressure. See Appendix B of this Instruction for information regarding testing methods for AIIRs. Also see 2005 CDC Guidelines, pp. 65-66.

AIIRs should have an air change rate of ≥ 6 mechanical air changes per hour (ACH). Whenever feasible, the airflow rate should be raised to ≥ 12 mechanical ACH by adjusting or modifying the ventilation system or supplementing with air cleaning technologies. Achieving a total air change rate of ≥ 12 mechanical ACH should be a goal when designing new AIIRs or renovating existing AIIRs. See 2005 CDC Guidelines, p. 66.

Booths, tents, or hoods that discharge exhaust air into the room they are located in should incorporate HEPA filters at the discharge duct; the exhaust fan should be on the discharge side of the filter. If the device does not incorporate a HEPA filter, the exhaust should be exhausted directly to the outside and not recirculated. See 2005 CDC Guidelines, p. 61.

Provisions should be made for emergency power to prevent interruptions in the performance of critical controls during a power outage (2005 CDC Guidelines, p. 75). If there is no emergency power, the system should have dampers installed to isolate the AIIR or treatment room in the event of a power failure to prevent the backflow of contaminated air. If dampers are not automated, the facility should have a written procedure to initiate the timely closure of dampers if a power failure is detected.

3. Citations under section 5(a)(1), and notices under 29 CFR 1960.8(a), shall be issued in accordance with the applicable provisions of Chapter 4 of the FOM and this Instruction. All abatement methods identified as potential means of correcting a given hazard should be listed in a single citation or notice.

4. For purposes of citing Section 5(a)(1) or issuing a notice under 1960.8(a), recognition of the hazard associated with the types of exposures discussed in section XVI.A.1 of this Instruction may be shown by referring to the 2005 CDC Guidelines; the CDC is an acknowledged body of experts familiar with these hazards. The 2005 CDC Guidelines should be consulted both for evidence of hazard recognition and for assistance identifying feasible methods of abatement.

5. If issuing a TB-related citation under Section 5(a)(1), or a notice under 1960.8(a), the Alleged Violation Description (AVD), after identifying the Standard Alleged Violation Element (SAVE), should state:

"On or about [date], the employer did not furnish employment and a place of employment which were free from recognized hazards that were causing or likely to cause death or serious physical harm in that employees were exposed to the hazard of being infected with *M. tuberculosis* through insufficiently protected contact with [*specify group such as patients, inmates, residents, clients, etc.*] who was/were infectious or suspected to be infectious with tuberculosis because: *[describe relevant circumstances]*."

"Feasible and useful abatement methods for reducing this hazard include, but are not limited to: *[list abatement methods]*."

NOTE: Refer to the 2005 CDC Guidelines, Appendix A, for a summary of recommended administrative, environmental, and respiratory protection controls for selected healthcare settings.

6. Hazard Alert Letters. In circumstances in which the Area Director, in consultation with the Regional Office of the Solicitor and the OSHA Regional and National Offices, determines that citations under the General Duty Clause, or notices under 1960.8(a), are not supported by the requisite evidence, he or she should consider issuing Hazard Alert Letters, in appropriate cases, to notify employers about the dangers of occupational exposure to TB and to provide information about methods that may be used to protect workers from those hazards. A sample Hazard Alert Letter may be found at Appendix D of this Instruction.

B. **Respiratory Protection** - 29 CFR 1910.134:

Paragraph (a)(2) of OSHA's Respiratory Protection Standard states: "A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in" 29 CFR 1910.134(c).

1. Requirements for an Acceptable Respirator Program.

The 2005 CDC Guidelines specify standard performance criteria for respiratory protection against exposure to TB. Under the 2005 CDC Guidelines, non-powered, air-purifying particulate-filter respirators with N95, N99, N100, R95, R99, R100, P95, P99, or P100 filters (including filtering facepieces (dust masks)), powered air-purifying respirators (PAPRs) with HEPA filters, or positive-pressure airline (supplied air) respirators may be used for protection against airborne *M. tuberculosis*. See 2005 CDC Guidelines, pp. 75-76.

The CDC recommends that employees wear, at a minimum, a NIOSH approved N95 filtering facepiece respirator (non-powered, air-purifying half facepiece) when respiratory protection is needed due to TB hazards (2005 CDC Guidelines, pp. 39-40). Such circumstances may include:

a) When employees enter rooms housing individuals with suspected or confirmed infectious TB disease;

b) When emergency medical response personnel or other workers transport, in a closed vehicle, an individual with suspected or confirmed infectious TB disease; and

c) When employees are present during the performance of cough-inducing or aerosol-generating procedures (e.g., bronchoscopy, sputum induction, autopsy, and selected laboratory procedures) on individuals who have suspected or confirmed infectious TB disease. See 2005 CDC Guidelines, pp. 38-39.

NOTE: The risk assessment for a particular setting might identify circumstances for which a higher level of respiratory protection (e.g., PAPRs) is necessary to provide adequate protection.

2. Citation Guidance for Respiratory Protection

a) When respiratory protection is required, the employer must establish and maintain a respiratory protection program in accordance with 29 CFR 1910.134(c). A citation based on an employer's failure to implement components of a respiratory protection program should be issued under the appropriate paragraph(s) of 29 CFR 1910.134. See CPL 02-00-158, *Inspection Procedures for the Respiratory Protection Standard*, June 26, 2014.

NOTE: If a facility chooses to use disposable N95 respirators as part of its respiratory protection program, each respirator can be reused by the same worker as long it maintains its structural and functional integrity and the filter material is not physically damaged or soiled. Disposable respirators must be stored in accord with 29 CFR 1910.134(h)(2) between uses. The facility's infection control procedures should establish polices for identifying when a disposable respirator will be deemed contaminated and unsuitable for reuse.

b) A citation based on an employer's failure to provide respirators necessary to protect employees from TB hazards should be issued under 29 CFR 1910.134(a)(1) or (a)(2), as appropriate.

c) A citation based on an employer's failure to identify and evaluate TB-related respiratory hazards in the workplace should be issued under 29 CFR 1910.134(d)(1)(iii).

NOTE: The respiratory hazard evaluation requirement is performance-oriented, and a variety of methods may be used to identify and evaluate potential employee exposures. Employers, however, are expected to take into account all relevant information relating to potential respiratory hazards.

d) A citation based on an employer's failure to ensure that employees using any negative or positive pressure tight-fitting facepiece pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) should be issued under the appropriate paragraph of 29 CFR 1910.134(f).

3. Sample AVD language for citations issued under 29 CFR 1910.134(a)(2):

"On or about [date], the employer did not provide suitable respirators when necessary to protect employee health:

Employees engaging in [describe task] were [not provided with respirators for protection against airborne tuberculosis] or [were provided only with (describe surgical mask or other protection used) for protection against airborne tuberculosis]. At a minimum, an N95 NIOSH-certified filtering facepiece respirator is necessary to protect employees from airborne TB."

C. PPE - 29 CFR 1910.132:

This section provides guidance to help CSHOs evaluate employers' compliance with OSHA's PPE standards. A citation based on an employer's failure to provide or ensure the use of PPE should be issued under the appropriate provision of the PPE standards for the particular hazard addressed. See CPL 02-01-050, *Enforcement Guidance for Personal Protective Equipment in General Industry*, February 10, 2011.

1. A citation based on an employer's failure to conduct a hazard assessment to determine the need for PPE (such as faceshields, goggles, or safety glasses with side shields to protect an employee from splashes and droplet sprays) should be issued under 29 CFR 1910.132(d)(1).

2. A citation based on an employer's failure to provide or ensure the use of PPE necessary to protect against splashes and droplet sprays of infectious material should be issued under 29 CFR 1910.132(d)(1)(i).

3. A citation based on an employer's failure to provide training to each employee required to use PPE should be issued under 29 CFR 1910.132(f)(1).

D. **Specifications for Accident Prevention Signs and Tags - 29 CFR 1910.145**:

This section provides CSHOs with guidance regarding enforcement of 29 CFR 1910.145.

1. A citation based on an employer's failure to post a biological hazard tag outside rooms where there is potential for TB exposure should be issued under 29 CFR 1910.145(f)(8)(i).

2. A citation based on an employer's failure to utilize hazard warning tags with a proper signal word (i.e., "Danger," "Caution," "Biological Hazard," or "BIOHAZARD") or the biological hazard symbol should be issued under 29 CFR 1910.145(f)(4)(i)(A).

3. A citation based on an employer's failure to provide a major message on the biological hazard tag that indicates the specific hazardous condition or the instruction to be communicated to employees should be issued under 29 CFR 1910.145(f)(4)(i)(B).

4. A citation based on an employer's failure to inform employees about the meaning of a biological hazard tag, and the precautions they need to take when they see such a tag, should be issued under 29 CFR 1910.145(f)(4)(v).

5. A citation based on an employer's failure to utilize biological hazard tags on air transport components (e.g., fans, ducts, filters) to identify TB hazards to employees working on the equipment should be issued under 29 CFR 1910.145(f)(8)(i).

6. Sample AVD language for failure to post a biological warning tag:

   On or about [date], a warning tag identifying actual or potential exposure to *M. tuberculosis* was not posted [describe location].

E. **Access to Employee Exposure and Medical Records - 29 CFR 1910.1020**:

This section provides CSHOs with guidance concerning access to employee medical records.

1. A record documenting employee exposure to TB is an employee exposure record within the meaning of 29 CFR 1910.1020(c)(5). Where known, an employee exposure record should contain a notation of the type of TB to which the employee was exposed (e.g., multi-drug resistant TB).

2. Records of TB skin test results and medical evaluations and treatment are employee medical records for purposes of 29 CFR 1910.1020.

3. Medical records must be handled according to 29 CFR 1913.10, Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records. See also CPL 02-02-072, *Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records*, August 22, 2007.

F. **Recording and Reporting Occupational Injuries and Illnesses - 29 CFR Part 1904**:

This section provides guidance to CSHOs regarding the enforcement of recordkeeping requirements. See CPL 02-00-135, *Recordkeeping Policies and Procedures Manual*, December 30, 2004.

1. Under 29 CFR 1904.11(a), for OSHA recordkeeping purposes, covered employers must record TB cases when an employee has been occupationally exposed to anyone with a known case of active TB and the employee subsequently develops TB infection evidenced by a positive skin test or diagnosed by a physician or other licensed health care professional. The case must be recorded by checking the "respiratory condition" column on the OSHA 300 Log. However, the case need not be recorded (or can be erased) if: (1) the worker lives in a household with a person diagnosed with active TB; (2) the Public Health Department identified the worker as a contact of a person with active TB (where contact is unrelated to the workplace); or (3) a medical investigation shows that the employee's infection was caused by exposure away from work or that the case was not related to the workplace TB exposure. See 29 CFR 1904.11(b)(2).

2. If a case of LTBI entered on the OSHA 300 log progresses to active TB disease during the 5-year record retention period, the original entry for the infection on the OSHA log must be updated to reflect the new employee information. See 29 CFR 1904.33(b)(1). Although in such cases it may be difficult to determine if TB disease resulted from the source indicated by the skin test conversion or from subsequent exposures, only one case should be entered on the OSHA 300 log to avoid double counting.

XVII. **Expert Witness**.

The Directorate of Technical Support and Emergency Management can help identify expert assistance when 5(a)(1) citations or notices under 29 CFR 1960.8(a) are being considered. In the event that a 5(a)(1) citation is contested, proper expert witness support may be needed. Issues that experts should be able to address include:

A. The risk to employees associated with the circumstances of employee exposure to TB.

B. The existence, feasibility and utility of abatement measures.

C. Recognition of the hazard within the industry.

XVIII. **OSHA Information System (OIS) Coding**.

All enforcement activities (inspections, complaints, and referrals) and compliance assistance interventions conducted under this Instruction must be coded "N 02 TB" in the appropriate OIS field on the OIS form.

XIX. **Referrals.**

A. When a complaint or inquiry is received from a source in a State Plan state regarding occupational exposure to TB, the Area Office must refer it to the State Plan state designee for action.

B. When a complaint or inquiry regarding occupational exposure to TB in a state or local government healthcare facility is received in a state without an OSHA-approved State-Plan, the Regional Administrator must refer it to the appropriate state public health agency or local health agency.

XX. **Pre-citation Review**.

Citations or notices proposed in accord with this Instruction should be reviewed prior to issuance by the Regional Administrator and Regional Solicitor's Office

for consistency with these procedures. The Directorate of Technical Support and Emergency Management should be contacted to facilitate expert witness support as needed.

Appendix A: Terms and Definitions

For more information about TB-related terms and definitions, please refer to the 2005 CDC Guidelines, pp. 103-119.

Air Changes Per Hour (ACH): Air change rate expressed as the number of air exchange units per hour. ACH is the number of times per hour that the total volume of air in an enclosure or room is replaced with clean air from the ventilation system or other air supply system.

Airborne Infection Isolation Room (AIIR): A room designed to maintain Airborne Infection Isolation (AII). AIIRs are single-occupancy patient-care rooms used to isolate persons with suspected or confirmed infectious TB disease. Environmental factors are controlled in AIIRs to minimize the transmission of infectious agents that are usually spread from person to person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AIIRs should be maintained under negative pressure (so that air flows under the door gap into the room), at an air flow rate of 6–12 ACH, and there should be direct exhaust of air from the room to the outside of the building or recirculation of air through a HEPA filter.

Bacille Calmette-Guerin (BCG): A vaccine for TB that is used in most countries where TB disease is endemic.

Blood Assay for Mycobacterium tuberculosis (BAMT): A general term that refers to recently developed in vitro diagnostic tests for the presence of infection with *M. tuberculosis*. This term includes, but is not limited to, interferon gamma release assays (IGRA).

Boosting: In some persons who had remote infections with *M. tuberculosis* or other *mycobacteria* or who had previous BCG vaccinations, the ability to react to tuberculin may wane over time. When given a TST years after infection, these persons may have a false-negative reaction. However, the TST may stimulate the immune system, causing a positive or boosted reaction to subsequent tests. Giving a second TST after an initial negative TST (two-step testing) can reduce the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

Healthcare Setting: Any setting in which healthcare is delivered and workers might share air space with persons with TB disease or come in contact with clinical TB specimens. This term is broader than the term "facility," which refers to a building or set of buildings. Examples of healthcare settings are inpatient settings (e.g., patient rooms), outpatient settings (e.g., TB treatment facilities and dental clinics), and non-traditional facility-based settings (e.g., medical settings in correctional facilities).

Infection Control Program: A multidisciplinary program that includes activities to ensure that recommended practices for the prevention of infections are implemented and followed by workers to prevent the spread of infection to patients and other personnel.

*Latent TB Infection (*LTBI*)*: Infection with *M. tuberculosis* without exhibiting symptoms or signs of disease. Persons with LTBI do not feel sick and do not have any symptoms. They are infected with *M. tuberculosis*, but do not have active TB disease. The only sign of TB infection is a positive reaction to the TST or a positive BAMT. **Persons with latent TB infection are not infectious and cannot spread TB infection to others**. Latent TB is often treated to prevent TB disease, although clinicians also take into account the individual's age, the duration of the latent infection, if known (progression to disease is much more likely within the first two years following infection), and the potential side effects from medication.

Multidrug-Resistant TB (MDR TB): TB that is resistant to at least two of the best anti-TB drugs, currently isoniazid and rifampin. Extremely drug-resistant TB (XDR TB) is a relatively rare type of MDR TB. XDR TB is defined as TB that is resistant to isoniazid and rifampin, as well as to any fluoroquinolone, and to at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). Because XDR TB is resistant to first-line and second-line drugs, patients are left with treatment options that are much less effective.

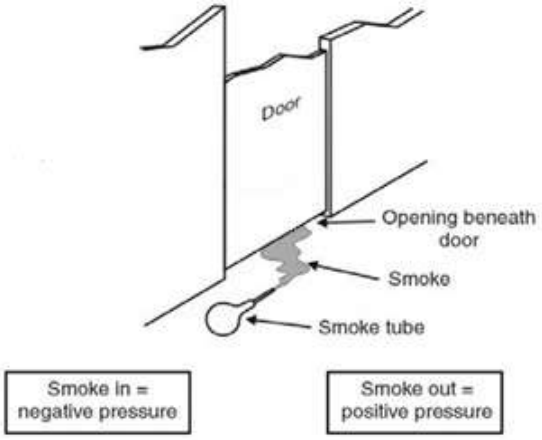
TB Disease: A condition caused by infection with *M. tuberculosis* or other mycobacteria that has progressed to causing clinical or subclinical illness, meaning there are signs or symptoms of disease or other indications of disease activity (e.g., the ability to culture reproducing TB organisms from respiratory secretions). *M. tuberculosis* can attack any part of the body, but the disease is most commonly found in the lungs (pulmonary TB). Pulmonary TB disease can be infectious, whereas extra-pulmonary disease (occurring somewhere other than the lungs) is infectious only in rare circumstances.

TB skin test (TST): TST is the standard method of determining whether a person is infected with *M. tuberculosis*. The TST is performed by injecting tuberculin PPD into the inner surface of the forearm. The skin test reaction should be measured by trained personnel between 48 and 72 hours after administration.

Appendix B: Testing Methods for Airborne Infection Isolation Rooms

A. **Test Method Description**:

One of the purposes of an AIIR is to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AIIRs need to be maintained under negative pressure. Smoke tubes or other visual checks can qualitatively confirm that the pressure differential is inducing airflow from the corridor through the crack at the bottom of the door (undercut) or through the air transfer grille (if the door has such a feature) and into the isolation room. Some AIIRs have differential pressure-sensing devices (e.g., manometers) to quantitatively measure the pressure differential. Smoke testing will qualitatively confirm the pressure-sensing device is functioning. See figure below (2005 CDC Guidelines, p. 65) for a demonstration of how smoke tube testing and manometer placement can be used to determine the direction of airflow into and out of a room.



B. **Recommendations for performing a smoke-tube test (where applicable)**:

1. Test only with the isolation door shut. If there is no anteroom, assume that there will be a loss of space pressure control when the isolation door is opened and closed. It is not necessary to demonstrate the direction of airflow when the door is open.

2. If there is an anteroom, release smoke at the inner door undercut or air transfer grille, with both anteroom doors shut.

3. In addition to a pedestrian entry, some isolation rooms also have a wider wheeled-bed stretcher door. Release smoke at all door entrances to isolation rooms.

4. So that the smoke is not improperly blown into the isolation room, hold the smoke bottle/tube parallel to the door so that the smoke is released at a right angle to the direction of airflow through the door undercut.

5. Position the smoke bottle/tube tight to the floor, centered in the middle of the door jamb and approximately 2 inches out in front of the door.

6. Release a puff of smoke and observe the resulting direction of airflow. Repeat the test at least once or until consistent results are obtained.

7. The amount of smoke needed to verify the air flow pattern should be minimized. Squeezing the bulb or bottle slowly should minimize the momentum given to the smoke as well as the volume of smoke released.

8. Depending on the velocity of the air through the door undercut, the smoke plume will either stay disorganized or it will form a distinct streamline. In either case, the smoke will react in one of three ways. It will:

   a. go through the door undercut into the isolation room,

   b. remain motionless, or

   c. be blown back into the corridor.

   Negative pressure is evident when the smoke is drawn into the isolation room through the door undercut.

9. If the room is occupied and it is determined necessary to evaluate relative room pressure, release smoke from the corridor side of the door only. Smoke testing should not be conducted in occupied rooms unless it can be determined that there is no potential respiratory impact on the patient.

10. If the room is unoccupied, release smoke inside the isolation room (same position as in the diagram above) to verify that released smoke remains contained in the isolation room (i.e., smoke is used as a surrogate for TB droplet nuclei).

11. If photography or videotaping is performed, a dark surface should be placed on the floor to maximize contrast. Be aware that most autofocusing cameras cannot focus on smoke.

C. **Testing "As Used" Conditions**:

Testing of an AIIR should reflect "as-used" conditions. Consider the following use variables which may affect space pressurization and the performance of the AIIR:

1. Patient toilet rooms are mechanically exhausted to control odors. The position of the toilet room door may affect the pressure differential between the isolation room and the corridor. Smoke tube tests should be performed with the toilet room door open and the toilet room door closed. This will not be necessary if the toilet room door is normally closed and controlled to that position by a mechanical door closer.

2. An open window can adversely affect the performance of an AIIR. If the isolation room is equipped with an operable window, perform smoke-tube tests with the window open and the window closed.

3. There may be corridor doors that isolate the respiratory ward or wing from the rest of the facility. These corridor doors are provided in the initial design of the building to facilitate space pressurization schemes and/or building life safety codes. Direct contact with the rest of the facility may cause pressure transients in the corridor (e.g., proximity to an elevator lobby) and affect the performance of the isolation room. Perform isolation room smoke-trail testing with these corridor doors in their "as-used" position which is either normally open or normally closed.

4. Isolation rooms may be equipped with auxiliary, fan-powered, recirculating, stand-alone HEPA filtration or UV units. These units should be running when smoke-tube tests are performed.

5. Do not restrict corridor foot traffic while performing smoke-tube tests.

6. Negative pressure is accomplished by exhausting more air than is supplied to the isolation room. Some heating, ventilation, air conditioning (HVAC) systems employ variable air volume (VAV) supply air and sometimes VAV exhaust air. By varying the supply air delivered to the space to satisfy thermal requirements, these VAV systems can adversely impact the performance of an AIIR. If the isolation room or the corridor is served by a VAV system, perform the smoke test twice. First, perform the smoke test with the zone thermostat thermally satisfied, and second, perform the test with the zone thermostat thermally unsatisfied, thus simulating the full volumetric flow-rate range of the VAV system serving the area being tested.

Appendix C: CSHO Checklist for Conducting TB-Related Inspections

This non-mandatory checklist is intended as a quick reference tool for Compliance Safety and Health Officers (CSHOs) conducting TB-related inspections. The CSHO may wish to review the checklist before completing the inspection to make sure that important considerations have not been overlooked. This checklist addresses topics discussed in Sections XIII and XVI, Inspection Procedures and Violations, respectively, of this Instruction. This checklist includes selected recommendations from the 2005 CDC Guidelines, many of which are discussed more extensively elsewhere in this Instruction. Checklist items include appropriate references to the 2005 CDC Guidelines and OSHA standards.

__ Suspected or confirmed TB case within previous 6 months. If not, TB-portion of inspection should be suspended.

__ Written TB Infection Control Plan (2005 CDC Guidelines, pp. 8-9)
- __ Protocol for early identification of individuals with suspected or confirmed TB
- __ Updated annually
- __ Supervised by qualified person or group

__ TB Risk Assessment (2005 CDC Guidelines, pp. 9-10)
- __ Initial risk evaluation for TB transmission conducted
- __ On-going evaluation of risk for TB transmission conducted
- __ Appropriate TB risk classifications assigned

__ Medical Surveillance
- __ Employees offered initial BAMT or TST (2005 CDC Guidelines, p. 28)
- __ If TST is used, did two-step baseline when necessary (2005 CDC Guidelines, p. 29, Box 1)
- __ BAMT or TST offered at no cost to employee
- __ Periodic screening conducted in accordance with Appendix C of the 2005 CDC Guidelines

__ Training (2005 CDC Guidelines, p. 27)
- __ Workers, including physicians, receive documented initial training relevant to their work settings
- __ Workers, including physicians, receive retraining in infection control procedures when potential or known exposure to TB occurs

__ Engineering Controls
- __ AIIRs are single-patient (2005 CDC Guidelines, p. 17)
- __ AIIRs have private bathrooms (2005 CDC Guidelines, p. 17)
- __ AIIRs ≥6 ACH or ≥12 where feasible and after new construction/renovation (2005 CDC Guidelines, p.37)
- __ AIIRs checked daily for negative pressure (2005 CDC Guidelines, p. 17)
- __ Ventilation: single-pass, non-recirculating exhaust direct to outside; or, HEPA filtration prior to recirculation into general ventilation; or HEPA filtration and UVGI

with room-air recirculation units (2005 CDC Guidelines, p.37)
- __ Pressure sensing device installed to determine need for HEPA filter replacement (2005 CDC Guidelines, p.69)
- __ Filter housing and ducts with warning labels (2005 CDC Guidelines, p.69)
- __ Documentation of preventive maintenance on TB ventilation systems (2005 CDC Guidelines, p.74)

__ Respiratory Protection
- __ Workplace respiratory hazard evaluation complete [29 CFR 1910.134(d)(1)(iii)]
  - __ Written respiratory protection program [29 CFR 1910.134(c)]
  - __ Medical evaluations [29 CFR 1910.134(c)(1)(ii)]
  - __ Fit testing procedures for tight-fitting respirators [29 CFR 1910.134(c)(1)(iii)]
  - __ Procedures for respirator use [29 CFR 1910.134(c)(1)(iv)]
  - __ Procedures for storage, cleaning, inspection [29 CFR 1910.134(c)(1)(v)]
  - __ Training [29 CFR 1910.134(c)(1)(vii)]
- __ Workers wear ≥N95 for TB hazards (2005 CDC Guidelines, pp. 39-40)
  - __ Fit factor ≥100 for disposable and half facepiece respirators (2005 CDC Guidelines, p. 39)
- __ Maintenance personnel working on ventilation systems probably contaminated with TB wearing respiratory protection, eye protection, and gloves (2005 CDC Guidelines, p. 69)

Appendix D: Sample Hazard Alert Letter - Tuberculosis

Note: The letter below is an example of the type of letter that may be appropriate in some circumstances. It must be adapted to the specific circumstances noted in the relevant inspection. If the employer has implemented, or is in the process of implementing, efforts to address hazardous conditions, those efforts should be recognized and encouraged, if appropriate.

Italicized comments are for OSHA compliance use only and should not be included in the letter.

Dear Employer:

An inspection and evaluation of your workplace at (location) on (date) disclosed the following workplace conditions which raise concerns about the potential for employee illness(es) related to exposure to mycobacterium tuberculosis (TB).

[Include a general description of the working conditions at issue and the nature of OSHA's concerns for settings classified as medium risk and settings classified as having potential for ongoing transmission for TB. Address, as applicable, any lack of feasible engineering controls, lack of PPE, inappropriate PPE, etc.

For example:

Employees performing cough induction procedures on suspected or confirmed TB patients were not provided suitable respirators for use while doing these procedures.]

Based on the CDC's current guidelines, it is recommended that you take the following precautions to materially reduce your employees' exposure to the conditions listed above [*NOTE: Use only the items on the list which are appropriate for the hazards relevant to the particular inspection*]:

1. Administrative Controls: Managing the transmission of infectious diseases such as TB relies heavily on the implementation of administrative controls and good work practices. TB preparedness should involve planning for the implementation of administrative controls and good work practices to protect affected employees. The following are recommended controls:

    a) Develop measures to support expeditious triage and isolation (or cohorting) of suspected or confirmed TB patients to minimize unprotected employee exposure.

    b) Limit the number of persons entering isolation rooms to the minimum number necessary for patient care and support.

    c) Provide dedicated patient-care equipment for suspected or confirmed TB patients.

    d) Ensure use of appropriate Biosafety Level 2 or 3 practices and equipment in laboratory facilities that handle specimens from suspected or confirmed TB

patients to reduce the spread of TB to laboratory workers.

e) Limit patient transport when possible and appropriate (e.g., do portable chest films at the bedside instead of transporting the patient to the Radiology department).

f) Post signs on the entrances to Airborne Infection Isolation Rooms (AIIRs) or affected procedure rooms to communicate the entry requirements necessary for worker protection.

g) If tolerated, place facemasks on suspected or confirmed TB patients to reduce employees' exposure.

h) Consider offering enhanced medical surveillance and screening to workers who perform the riskiest tasks or activities.

2. Engineering Controls: Engineering controls are the first line of defense in worker protection. Therefore, employers should provide appropriate engineering controls, where feasible, and should train their employees in the use of those controls to ensure the protection of employees providing care to suspected or confirmed TB patients. The following are recommended controls:

a) Utilize AIIRs to reduce the spread of TB when performing aerosol-generating procedures such as:

- Bronchoscopy
- Sputum induction
- Endotracheal intubation and extubation
- Open suctioning of airway
- Cardiopulmonary resuscitation
- Autopsies

b) Air from AIIRs should be exhausted directly outside whenever possible; best practice incorporates filtration of this exhausted air.

c) If AIIRs are not available, increase air changes and avoid unfiltered recirculation of the room air or utilize negative pressure patient enclosure devices (e.g., tents or booths).

d) Where air must be recirculated, utilize HEPA filtration.

e) Use UVGI devices only in addition to HEPA filtration.

f) Filtration systems should be on maintenance schedules, and labeled and disposed of properly.

3. Personal Protective Equipment. Perform a workplace hazard assessment as required by 29 CFR 1910.132(d) to determine the tasks that necessitate the use of personal protective equipment (PPE) such as face masks, gloves, goggles, and respirators.

a) Provide gloves made of latex, vinyl, nitrile, or other synthetic materials, as appropriate, when there is contact with body fluids, including respiratory secretions.

b) Assure that employees wear appropriate protective clothing (e.g., an isolation gown) when it is anticipated that clothes or a uniform may get soiled with body fluids, including respiratory secretions.

c) Use eye and face protection if sprays or splatters of infectious material are likely. Goggles should be worn while performing aerosol-generating procedures. Use of a full face shield in front of a respirator may also prevent bulk contamination of the respirator.

d) If employees are using respiratory protection, establish, implement, and maintain a written respiratory protection program as required by 29 CFR 1910.134(c). *[The following are specific to respiratory protection use:]*

- Use NIOSH-certified respirators that are N95 or higher. When both fluid protection (e.g., blood splashes) and respiratory protection are needed, use a "surgical N95" respirator that has been certified by NIOSH and cleared by the FDA.

- Consider NIOSH-certified elastomeric respirators (e.g., cartridge respirators) for essential workers who may have to decontaminate and reuse respirators in the event that there is a shortage of disposable respirators.

- Consider NIOSH-certified powered air-purifying respirators (PAPRs) for circumstances (possibly bronchoscopy or autopsy on persons with suspected or confirmed TB disease and selected laboratory procedures) for which a level of respiratory protection that exceeds the minimum level provided by an N95 disposable respirator is necessary. Loose-fitting hooded PAPRs have the additional advantage of not requiring fit testing.

4. Training and Information: Provide training, education, and informational materials about the risk of TB exposure associated with workers' job tasks and activities.

a) If PPE will be used, explain why it is being used. Educate and train workers about the protective clothing and equipment appropriate to their current duties and the

duties they may be asked to assume when others are absent.

b) Explain how to use basic hygiene (e.g., hand washing, covering mouth and nose with a tissue when coughing or sneezing) and social distancing precautions that will be implemented and why they are effective.

c) Ensure materials are easily understood and available in the appropriate language and educational level for all workers.

d) Post signs asking workers, customers, and the general public to follow basic hygiene practices.

For more information, please refer to the Centers for Disease Control and Prevention (CDC), Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, 2005, MMWR December 30, 2005/ Vol. 54/ No. RR-17, and CDC Fact Sheets: General Information; Data & Statistics; Drug-Resistant TB; Infection Control & Prevention; TB in Specific Populations; Treatment; Testing & Diagnosis; and Vaccines & Immunizations.

You may voluntarily provide this Area Office with progress reports on your efforts to address TB hazards in your workplace. OSHA may return to your worksite to further examine the conditions noted above.

Enclosed is a list of available resources that may be of assistance to you in preventing work-related injuries and illnesses in your workplace. OSHA Compliance Assistance Specialists are available to assist with presentations and to provide further information on TB hazards. If you have any questions, please feel free to call [name and phone number] at [address].

Sincerely,

Area Director