

**OREGON OCCUPATIONAL SAFETY AND HEALTH DIVISION
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES**

PROGRAM DIRECTIVE

Program Directive: **A-215**

Issued: January 22, 1997

Revised: June 30, 2009

SUBJECT: Tuberculosis: Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis

AFFECTED STANDARDS/

DIRECTIVES: 654.010 of the Oregon Safe Employment Act
OAR 437-002-1910.134 Respiratory Protection
OAR 437-002-1910.145 Accident Prevention Signs & Tags
OAR 437-002-1910.1020 Access to Employee Exposure and Medical records
OAR 437-001-0700 Recordkeeping and Reporting

ACTION: This directive will be followed when potential exposures to tuberculosis (TB) are found in the workplace.

EFFECTIVE DATE: This directive is effective immediately and will remain in effect until canceled or superseded.

A. PURPOSE: This instruction provides uniform inspection procedures and guidelines when conducting inspections and issuing citations under ORS 654, the Oregon Safe Employment Act, and pertinent standards for employees who are occupationally exposed to tuberculosis.

B. SCOPE: This instruction applies to all of Oregon OSHA.

C. REFERENCES:

1. Field Inspection Reference Manual (FIRM).
2. American Public Health Association - 2004 or current edition, Control of Communicable Diseases Manual.
3. Oregon OSHA Technical Manual.
4. Centers for Disease Control and Prevention (CDC), Biosafety in Microbiological and Biomedical Laboratories (BMBL), Fifth Edition 2007, or current edition.

5. Department of Health and Human Services, Public Health Service, 42 CFR Part 84; Final Rule.
6. Centers for Disease Control and Prevention (CDC); Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, MMWR December 30, 2005; 54 (RR17); 1-141.

The Web link for Centers for Disease Control and Prevention (CDC): Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005 is <http://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf>.

A hard copy of the CDC Guidelines can be obtained by calling the Oregon OSHA Resource Center at 800-922-2689 or 503-378-3272 when internet access is not available.

7. List of Major Errata in Order of Importance from the “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005.”
8. Extensively Drug-Resistant Tuberculosis; United States, 1996 - 2006; MMWR March 23, 2007; 56(11); pp 250-253.
9. Centers for Disease Control and Prevention (CDC); Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC, 2006; MMWR July 7, 2006; 55 (RR09); 1-44

D. ACTION:

Oregon OSHA must use this instruction to ensure uniformity when performing inspections for occupational exposures to TB.

E. RESERVED

F. DEFINITIONS:

For a complete list of definitions applicable to TB, refer to the glossary of definitions in the 2005 CDC Guidelines.

G. BACKGROUND:

The CDC reassessed the TB infection control guidelines for healthcare settings because of the changes in epidemiology and a request by the Advisory Council for the Elimination of Tuberculosis (ACET) for them to review and update the 1994 TB infection control document. The CDC Guideline updates reflect shifts in the epidemiology of TB, advances in scientific understanding, and changes in healthcare practice that have occurred in the United States in the previous decade. In the context of diminished risk for healthcare-associated transmission of *M. tuberculosis*, CDC Guidelines emphasize actions to

maintain momentum and expertise needed to avert TB resurgence and eliminate the lingering threat to healthcare workers (HCWs), which is primarily from patients or other people with unsuspected and undiagnosed infectious TB.

CDC prepared the guidelines in consultation with experts in TB, infection control, environmental control, respiratory protection, and occupational health. Those guidelines replaced all previous CDC Guidelines for TB infection control in healthcare settings. Primary references citing evidence-based science are used to support explanatory material and recommendations.

The following changes differentiate the 2005 CDC Guidelines from previous guidelines:

- The risk assessment process includes the assessment of additional aspects of infection control.
- The term “tuberculin skin tests” (TSTs) is used instead of purified protein derivative (PPD).
- The whole-blood interferon gamma release assay (IGRA), QuantiFERON®-TB Gold test (QFT-G) (Cellestis Limited, Carnegie, Victoria, Australia), is approved by the Food and Drug Administration (FDA) in vitro cytokine based assay for cell-mediated immune reactivity to *M. tuberculosis* and might be used instead of TST in TB screening programs for HCWs. This IGRA is an example of a blood assay for *M. tuberculosis* (BAMT).
- The frequency of TB screening for HCWs has been decreased in various settings, and the criteria for determination of screening frequency have been changed.
- The scope of settings in which the guidelines apply has been broadened to include laboratories and additional outpatient and nontraditional facility-based settings.
- Criteria for serial testing for *M. tuberculosis* infection of HCWs are more clearly defined. In certain settings, this change will decrease the number of HCWs who need serial TB screening.
- These recommendations usually apply to an entire healthcare setting rather than areas within a setting.
- New terms airborne infection precautions (airborne precautions) and airborne infection isolation room (AII room) are introduced.
- Recommendations for annual respirator training, initial respirator fit testing, and periodic respirator fit testing have been added.

- The evidence of the need for respirator fit testing is summarized.
- Information on ultraviolet germicidal irradiation (UVGI) and room-air recirculation units has been expanded.
- Additional information regarding multi-drug-resistant (MDR) TB and HIV infection has been included.

According to relevant local, state, and federal laws, implementation of all recommendations must safeguard the confidentiality and civil rights of all HCWs and patients who have been infected with *M. tuberculosis* and TB.

The 1994 CDC Guidelines were aimed primarily at hospital-based facilities, which frequently refer to a physical building or set of buildings. The 2005 guidelines have been expanded to address a broader concept. “Setting” has been chosen instead of “facility” to expand the scope of potential places where these guidelines apply (Appendix A of the guidelines). “Setting” is used to describe any relationship, physical or organizational, where HCWs might share air space with people with TB, or where HCWs might be in contact with clinical specimens. Various setting types might be present in a single facility. Healthcare settings include inpatient settings, outpatient settings, and nontraditional facility-based settings.

Drug resistant strains of *M. tuberculosis* have become a serious concern and cases of MDR TB have occurred in forty states. Also, extensively drug-resistant tuberculosis (XDR TB) has been reported in nine states.

M. tuberculosis is usually transmitted only through air, not by surface contact. It is carried through the air in tiny infectious droplet nuclei of 1 to 5 micrometers in diameter. These droplets may be generated when a person with pulmonary and laryngeal TB coughs, speaks, sings, sneezes, or spits. When inhaled by susceptible people, 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., TB. Transmission of TB is most likely to occur from people with pulmonary or laryngeal TB that are not on effective anti-TB therapy and who have not been placed in respiratory isolation.

In occupational healthcare settings, where patients with TB are seen, workers exposed to tuberculosis droplet nuclei are at increased risk of infection with exposure to TB. Certain high-risk medical procedures that are cough-inducing or aerosol generating

can further increase the risk of infection in healthcare workers.

The employer's obligations are those set forth in the Oregon Safe Employment Act (OSEAct) of 1973. Recommendations for preventing the transmission of TB for healthcare settings were originally established with the 1990 CDC Guidelines. In October of 1994, those guidelines were revised and published. In 2005, the CDC Guidelines were revised once again. Those guidelines emphasized the control of TB through an effective TB infection control program. Under these guidelines the control of TB is to be accomplished through the early identification, isolation, and treatment of people with TB, use of engineering and administrative procedures to reduce the risk of exposure, and through the use of respiratory protection. Oregon OSHA believes these guidelines reflect industry recognition of the hazard as well as appropriate, widely recognized, and accepted standards of practice to be followed by employers in carrying out their responsibilities under the OSEAct.

H. INSPECTIONS Of HEALTHCARE SETTINGS AND SCOPE:

1. The evaluation of occupational exposure to TB must be conducted in response to employee complaints, related fatality or catastrophes, or as part of all industrial hygiene inspections conducted in healthcare settings. Healthcare workers (HCWs) that might share air space with people with TB disease, come in contact with clinical specimens, serve patients in high risk populations, or HCWs with unprotected exposure to undiagnosed patients and without airborne precautions are at a higher risk for exposure to an infection with TB. The worker's degree of risk of occupational exposure to TB will vary based on a number of factors.

These healthcare settings have been the subject of reports issued by the CDC that provide recommendations for control of TB. Healthcare settings and HCWs who should be included in a TB surveillance program are identified on page 3 of the CDC Guideline. Specifically, these healthcare settings are as follows:

- a. Inpatient settings include patient rooms, emergency departments (EDs), intensive care units (ICUs), surgical suites, laboratories, laboratory procedure areas, bronchoscopy suites, sputum induction or inhalation therapy rooms, autopsy suites, and embalming rooms.

- b. Outpatient settings include TB treatment facilities, medical offices, ambulatory-care settings, dialysis units, and dental care settings.
 - c. Nontraditional facility-based settings include emergency medical service (EMS); medical settings in correctional facilities, such as prisons, jails, and detention centers; home-based healthcare and outreach settings; long-term care settings, such as hospice-skilled nursing facilities and homeless shelters. Other settings in which suspected and confirmed TB patients might be encountered might include cafeterias, general stores, kitchens, laundry areas, maintenance shops, pharmacies, and law enforcement settings.
2. All inspections in these workplaces must include a review of the employer's plans for employee TB protection, if any. Such plans may include the infection control program, respiratory protection, and skin testing. Employee interviews and site observations are an integral part of the process evaluation.
 3. CDC Guidelines emphasize the need for a TB infection-control plan. The plan should be designed to ensure prompt detection, airborne precautions, and treatment of people who have suspected or confirmed TB (or prompt referral of people suspected to have TB where TB is not expected to be encountered). Such a program is based on a three-level hierarchy of controls, including administrative, environmental, and respiratory protection.

I. INSPECTION PROCEDURES:

The procedure given in the FIRM, Chapter II, must be followed except as modified in the following sections:

1. Healthcare settings generally have internal infection control and employee health programs. This function may be performed by a team or individual. Upon entry, the CSHO must request the presence of the infection control director and employee occupational health professional responsible for occupational health hazard control. Other individuals who will be responsible for providing records pertinent to the inspection may include the training director, facilities engineer, director of nursing, etc.
2. The CSHO must establish whether or not the facility has had a suspect or confirmed TB case within the previous six months from the opening conference to determine coverage under the OSEAct. This determination may be based upon interviews and, in a hospital, a review of the infection control data.

3. If the facility has had a suspected or confirmed TB case within the previous six months, the CSHO must proceed with the TB portion of the inspection. The CSHO must verify implementation of the employer's plans for TB protection through employee interviews and direct observation where feasible. Professional judgment is used to identify which areas of a facility must be inspected during the walkthrough, such as emergency rooms, respiratory therapy areas, bronchoscopy suites, and morgue. After review of the facility plans for worker TB protection, employee interviews combined with an inspection of appropriate settings of the facility must be used to determine compliance.
4. CSHOs who perform smoke-trail visualization tests should review the protocol in Appendix B of this directive.
5. CSHOs should be prepared to present to the employer the material safety data sheet (MSDS) for the smoke that is released on smoke-trail visualization.

**J. FIELD STAFF
PROTECTION:**

1. Field managers will ensure that Oregon OSHA staff performing TB related inspections/consultations are familiar with the CDC Guidelines, terminology, and are adequately trained through either course work or field work experience in healthcare settings.
2. CSHOs must not enter occupied AII rooms to evaluate compliance unless they determine entry is required to document a violation. Prior to entry CSHOs will discuss the need for entry with the field manager. Photographs or video taping, where practical, must be used for case documentation. Under no circumstances shall photographing or videotaping of patients be done. CSHOs must take all necessary precautions to assure and protect patient confidentiality.
3. CSHOs must exercise professional judgment and extreme caution when engaging in activities that may involve potential exposure to TB. CSHOs normally establish the existence of hazards and adequacy of work practices through employee interviews and must observe them in a manner which prevents exposure, such as through an observation window where available.
4. On rare occasions when entry into hazardous areas is necessary, where the CSHO determines that direct observation of a high hazard procedure is necessary, the CSHO must consult with their supervisor and be properly equipped as required by the facility and

this directive. It is Oregon OSHA's policy to have CSHOs use the respiratory protection that is issued to them. Since CSHOs' respiratory protection is used in more than one type of industry, they must use their negative pressure elastomeric face piece respirators equipped with HEPA filters as the minimum level of respiratory protection.

5. CSHOs who conduct TB inspections must be offered the TB skin tests. CSHOs exposed to an individual(s) with active infectious TB must have a contact investigation conducted as outlined in pages 35-36 ("Contact Investigations") of the CDC Guideline.
6. If an AII room is occupied by a patient with confirmed or suspected TB or has not been adequately purged when a smoke-trail test is performed, then the CSHO should assume that the isolation room is not under negative pressure. Under such circumstances and the CSHO determines it's necessary to enter the room, CSHOs must wear a negative pressure HEPA respirator when performing smoke trail visualization testing as described in Appendix A of this directive.

**K. CITATION
POLICY:**

Follow relevant chapters of the FIRM when preparing and issuing citations for hazards related to TB.

The following requirements apply when citing hazards found in target workplaces. Employers must comply with the provisions of these requirements whenever an employee may be occupationally exposed to TB:

ORS 654, the Oregon Safe Employment Act
1910.134 Respiratory Protection
1910.145 Specifications for Accident Prevention Signs and Tags
1910.1020 Access to Employee Exposure and Medical Records
OAR 437-001-0700 Recordkeeping and Reporting

(Examples of each of the codes above are in the next section titled L. Violations.)

L. VIOLATIONS:

All elements in this section must be addressed to ensure adequate protection of employees from TB hazards. Violations of Oregon OSHA requirements will normally be classified as serious.

Transmission of *M. tuberculosis* is a risk in healthcare settings. The magnitude of the risk varies by setting, occupational group, prevalence of TB in the community, patient population, and effectiveness of TB infection control measures.

1. ORS 654, the Oregon Safe Employment Act

654.010 provides: “Every employer shall furnish employment and a place of employment which are safe and healthful for employees therein, and shall furnish and use such devices and safeguards, and shall adopt and use such practices, means, methods, operations and processes as are reasonably necessary to render such employment and place of employment safe and healthful, and shall do every other thing reasonably necessary to protect the life, safety and health of such employees.”

- a.** 654.010 citations must meet the requirements outlined in the FIRM, and issued only when there is no standard that applies to the particular hazard. The hazard, not the absence of a particular means of abatement, is the basis for a 654.010 citation. All applicable abatement methods identified as correcting the same hazard must be issued under a single 654.010 citation.
- b.** Recognition, for purposes of citing section 654.010, is shown by the CDC Guidelines for the types of exposures detailed below because the CDC is an acknowledged body of experts familiar with the hazard.
- c.** Citations will be issued to healthcare employers when they don’t provide their employees with appropriate protection, making them susceptible to the exposures defined below:

 - 1.** Exposure to the exhaled air of an individual with suspected or confirmed pulmonary TB, or
 - 2.** Employee exposure without appropriate protection to a high hazard procedure performed on an individual with suspected or confirmed infectious TB and which has the potential to generate infectious airborne droplet nuclei. Examples of high hazard procedures include aerosolized medication treatment, bronchoscopy, sputum induction, endotracheal intubation and suctioning procedures, emergency dental, endoscopic procedures, and autopsies conducted in hospitals.
- d.** If a citation under 654.010 is justified, the citation, after setting forth the standard alleged violation element (SAVE) for section 654.010, will state:

654.010 of the OSEAct: The employer did not furnish a safe

place of employment which is safe and healthful for employees therein, and did not furnish and use such devices and safeguards, and adopt and use such practices, means, methods, operations and processes which are reasonably necessary to render such employment and place of employment safe and healthful, and did not do every other thing reasonably necessary to protect the life, safety and health of such employees exposed to the hazard of being infected with *Mycobacterium tuberculosis* through unprotected contact with [specify group such as patients, inmates, clients, etc.] who was/were infectious or suspected to be infectious with tuberculosis in that: [list deficiencies].

Feasible and useful abatement methods for reducing this hazard, as recommended by the CDC, include, but are not limited to: [list abatement methods].

- e. The following are examples of feasible and useful abatement methods, which must be implemented to abate the hazard. Deficiencies found in any category can result in the continued existence of a serious hazard and may, therefore, allow citation under 654.010.
 1. Early identification of patient/client. The employer must implement a protocol for the early identification of individuals with active TB. See “Prompt Triage” under “Managing Patients Who Have Suspected or Confirmed TB: General Recommendations,” on page 16 of the CDC Guideline for specifics.
 2. TB surveillance. There are three TB screening risk classifications: **1) low risk, 2) medium risk, 3) potential ongoing transmission** on Page 10 of the CDC guideline (TB Screening Risk Classifications).

The classification of **low** risk should be applied to settings in which people with TB are not expected to be encountered; therefore, exposure to *M. tuberculosis* is unlikely. This classification should also be applied to HCWs who will never be exposed to people with TB or to clinical specimens that might contain *M. tuberculosis*.

The classification of **medium** risk should be applied to settings in which the risk assessment has determined that HCWs will or will possibly be exposed to people with TB or to clinical specimens that might contain *M. tuberculosis*.

The classification of **potential ongoing transmission** should be temporarily applied to any setting, or group of HCWs, if evidence suggests person-to-person, e.g., patient-to-patient, patient-to-HCW, HCW-to-patient, or HCW-to-HCW, transmission of *M. tuberculosis* has occurred in the setting during the preceding year.

- a. Initial screening.** The employer in covered workplaces must offer a baseline TST or a baseline blood assay for Mycobacterium tuberculosis (BAMT) at no cost to current potentially exposed employees and to new employees prior to exposure. The TB Infection Control Surveillance section of the CDC Guidelines discusses administering two-step TSTs when a single TST is adequate and when TSTs should not be administered. Box 1, pg 29 of the CDC Guidelines provides a good summary table. Tuberculin skin tests must be offered at a time and location convenient to workers. Follow-up and treatment evaluations are also to be offered at no cost to the workers.
- b. Additional screenings.** TSTs must be conducted every year for those HCWs working in healthcare settings with medium risk. HCWs with a baseline positive or newly positive test result for *M. tuberculosis* infection or documentation of previous treatment for latent TB infection (LTBI) or TB should receive one chest radiograph result to exclude TB. Instead of participating in serial testing, HCWs should receive a symptom screen annually. This screen should be accomplished by educating the HCW about symptoms of TB and instructing the HCW to report any such symptoms immediately to the occupational health unit.

Treatment for LTBI should be considered according to the CDC Guidelines. Where the setting or HCW is classified as “potential ongoing transmission,” TSTs might need to be conducted every 8-10 weeks, or until lapses in infection control have been corrected, and no additional evidence of ongoing transmission is apparent. BAMT can be used in screening programs.

Note: If the facility has not completed a risk assessment, the CSHO must review the TB related records to establish required testing frequencies for the facility and areas of the facility.

- c. Positive test results.** Any HCW with a newly recognized positive test result for *M. tuberculosis* infection, test conversion, or symptoms or signs of TB should be promptly evaluated. The evaluation should be arranged with employee health, the local or state health department, or a personal physician.
 - d. Contact investigations and screening.** Follow CDC guidelines, see page 35 under Contact Investigations, when HCW are exposed in a healthcare setting. Contact investigations should be collaboratively conducted by infection-control personnel and local TB-control personnel.
3. **Worker education and training.** Training and information to ensure employee knowledge of issues such as the mode of TB transmission, its signs and symptoms, medical surveillance and therapy, and site specific protocols including the purpose and proper use of controls must be provided to all current employees and to new workers upon hiring. (See pgs. 27-28 of the CDC Guidelines)

Workers must be trained to recognize, and report to a designated person, any patients or clients with symptoms suggestive of infectious TB and instructed on the post exposure protocols to be followed in the event of a TB exposure incident.

4. **Environmental Controls.** The use of each control measure must be based on its ability to abate the hazard.
- a.** Individuals with suspected or confirmed infectious TB must be placed in an AII room. High hazard procedures on individuals with suspected or confirmed infectious TB must be performed in AII rooms, booths, or hoods.
 - b.** AII rooms in use by individuals with suspected or confirmed infectious TB must be kept under negative pressure to induce airflow into the room from all surrounding areas, such as corridors, ceiling plenums, plumbing chases. (See page 17, “AII Room Practices”, of the CDC Guidelines.)

Note: The employer must assure that AII rooms are maintained under negative pressure. At a minimum, the employer must use nonirritating smoke trails or some other indicator to demonstrate that direction of airflow is from the corridor into the

isolation/treatment room with the door closed. If an anteroom exists, direction of airflow must be demonstrated at the inner door between the isolation/treatment room and the anteroom. (See Appendix A of this directive.)

- c.* Air exhausted from an AII room(s) should be safely exhausted directly outside 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.
- d.* Ultraviolet Germicidal Irradiation (UVGI) systems can also be used with limitations, but not in lieu of HEPA filtration where air is recirculated and a person with infectious TB may be present. The use of UV radiation as the sole means of decontamination must not be used. The CDC Guidelines allow use of UVGI in waiting rooms, emergency rooms, corridors, and other areas where patients with undiagnosed TB could contaminate the air. (See pages 36-38 “Environmental Controls” and Supplement, “Environmental Controls,” pages 60-75 of the CDC Guidelines for additional information.) For these HEPA filters, a regularly scheduled monitoring program to demonstrate as-installed effectiveness should include: 1) recognized field test method, 2) acceptance criteria, and 3) testing frequencies. The air handling system should be appropriately marked with a TB warning where maintenance personnel have access to the duct, fans, or filters for maintenance or repair.
- e.* In order to avoid leakage, all potentially contaminated air that is ducted through the facility must be kept under negative pressure until it is discharged safely outside, away from occupied areas and air intakes, or
- f.* The air from AII rooms must be decontaminated by a recognized process, such as HEPA filter, before being recirculated back to the AII room.

Note: Opening and closing doors in an AII room that is not equipped with an anteroom compromises the ability to maintain negative pressure in the room. For these rooms, the employer should use a combination of controls and practices to minimize spilling contaminated air into the corridor. Recognized controls and practices include, but are not limited to: minimizing entry to the room, adjusting the hydraulic closer to slow the door movement and reduce displacement effects, adjusting doors to swing into the room where fire codes permit, and avoiding

placement of room exhaust intake near the door.

- g.** High hazard procedures should be performed within an AII room, meeting the aforementioned specifications. Appropriate personal protective equipment, including respiratory protection, is required. The CDC Guidelines discuss situations when AII rooms are not available, e.g., intensive care units or surgical suites. If an AII is not available or appropriate, the HCW must wear adequate respiratory protection prior to entering the room and for the duration of the procedure. Afterward, a purge time interval must be imposed where personnel continue to use adequate respiratory protection.
- h.** Interim or supplemental ventilation units equipped with HEPA filters as described in the Supplement, Environmental Controls of the CDC Guidelines are acceptable, but not in lieu of the previously discussed environmental controls for an AII.

2. 1910.134 Respiratory Protection

1910.134(a)(2). The standard provides in part:

"Respirators shall be provided by the employer when such equipment is necessary to protect the health of the 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 protective program which shall include the requirement outlined in paragraph (c) of this section."

- a. Requirements for a minimal acceptable program.** The overall effectiveness of respiratory protection is affected by 1) the level of respiratory protection selected, such as the assigned protection factor, 2) the fit characteristics of the respirator model, 3) the care in donning the respirator, and 4) the adequacy of the fit-testing program. Data on the effectiveness of respiratory protection against hazardous airborne materials are based on experience in the industrial setting; data on protection against transmission of *M. tuberculosis* in healthcare settings are not available. The parameters used to determine the effectiveness of a respiratory protective device are face-seal efficacy and filter efficiency.

These parameters include: (see pg. 75 of the CDC Guidelines)

- 1. Filter penetration.** Aerosol penetration through respirator filters depends on at least five independent variables: 1)

filtration characteristics for each type of filter, 2) size distribution of the droplets in the aerosol, 3) linear velocity through the filtering material, 4) filter loading, e.g., amount of contaminant deposited on the filter, and 5) electrostatic charges on the filter and on the droplets in the aerosol (284).

When N95 disposable respirators are used, filter penetration might approach 5%, i.e., 50% of the allowable leakage of 10% for an N95 disposable respirator. When high efficiency filters are used in PAPRs or for half-facepiece respirators, filter efficiency is high, i.e., effectively 100%, and filter penetration is less of a consideration. Therefore, for high efficiency or 100-series filter respirators, the majority of inward leakage of droplet nuclei occurs at the respirator's face seal or exhalation valve.

2. Face-seal leakage is inherent in tight-fitting negative-pressure respirators. Each time a person wearing a nonpowered particulate respirator inhales, negative pressure, relative to the workplace air, is created inside the facepiece. Because of this negative pressure, air containing contaminants can leak into the respirator through openings at the face-seal interface and avoid the higher-resistance filter material. A half-facepiece respirator, including an N95 disposable respirator, should have <10% leakage. Full facepiece, nonpowered respirators have the same leakage (<2%) as PAPRs with tight-fitting full-facepieces. PAPRs with loose-fitting facepieces, hoods, or helmets have <4% inward leakage under routine conditions. Therefore, a PAPR might offer lower levels of face-seal leakage than nonpowered, half-mask respirators.
3. The ability to fit the different facial sizes and characteristics of health care workers which can usually be met by making the respirators available in at least three sizes.
4. The ability to be checked for face piece fit, according to OSHA standards and good industrial hygiene practice, by healthcare workers each time they put on their respirator.
5. Under the new NIOSH criteria, filter materials would be tested at a flow rate of 85 L/minute for penetration by particles with a median aerodynamic diameter of 0.3 μm and, if certified would be placed in one of the following

categories: Type 100 (99.7% efficient), Type 99 (99% efficient), and Type 95 (95% efficient). (See Appendix A and pg. 76 of the CDC Guidelines). NIOSH has determined these categories of respirators are effective against TB. Based upon these criteria, **the minimally acceptable level of respiratory protection for TB is the Type 95 Respirator**. The classes of these air-purifying, particulate respirators to be certified are described under 42 CFR Part 84 Subpart K. See Volume 60 of the Federal Register, page 30338 (June 8, 1995).

6. The following respiratory protection measures must be addressed:
 - a. Employees wear HEPA or respirators certified under 42 CFR Part 84 Subpart K in the following circumstances:
 1. When workers enter rooms with individuals with suspected or confirmed infectious TB.
 2. When workers are present while high hazard procedures are performed on individuals who have suspected or confirmed infectious TB.
 3. When administrative and environmental controls probably will not protect workers from inhaling infectious airborne droplet nuclei, such as transporting patients with suspected or confirmed infectious TB in vehicles, such as EMS vehicles or ambulances, and providing urgent surgical or dental care to patients with suspected or confirmed infectious TB (see Supplement, in the CDC Guideline, Estimating the Infectiousness of a TB Patient).
 - b. The following sample language is provided for citations warranted under 1910.134(a)(2):

"The employer did not provide respirators that were suitable for the intended purpose, nor was a respiratory protection program that included the requirements outlined in 1910.134 established.

Employees were given a [surgical mask or list manufacturer/model number] respirator for protection against airborne Mycobacterium tuberculosis when

entering isolation rooms or performing high hazard procedures [including vehicular transporting if applicable]. They must use NIOSH approved respirators: HEPA or those certified under 42 CFR Part 84 Subpart K. NIOSH approved respirators providing greater protection would also be acceptable.”

- c. When respiratory protection, including disposable respirators, is required, a complete respiratory protection program must be in place according to 1910.134.

3. Accident prevention signs and tags: 1910.145.

- a. According to 1910.145(f)(8), a warning must be posted outside the respiratory isolation or treatment room. 1910.145 (f)(4) requires that a signal word, e.g., “danger,” “caution,” “biological hazard,” or “biohazard” or a biological hazard symbol be presented as well as a major message, e.g., “special respiratory isolation,” “respiratory isolation,” or “AFB isolation.” A description of the necessary precautions, e.g., “respirators must be donned before entering AII rooms” or a message referring people to the nursing station for instruction must also be posted.

- b. The standard provides, in part:

1910.145(e)(4): Biological hazard warning signs were not used to signify the actual or potential presence of a biohazard and to identify equipment, containers, rooms, materials, experimental animals, or combinations thereof, which contain, or are contaminated with viable hazardous agents:

Sample violation language:

“On or about [date], warning signs posted outside respiratory isolation or treatment rooms did not state the entry requirement of wearing HEPA filtered respirators.”

4. Access to employee medical and exposure records: 1910.1020.

- a. A record concerning employee exposure to TB is an employee exposure record within the meaning of 1910.1020.
- b. A record of TST results and medical evaluations and treatment

are employee medical records within the meaning of 1910.1020. Where known, the workers exposure record should contain the type of TB the employee was exposed to, such as multidrug resistant TB.

- c. These records must be handled according to 1913.10 in order for the CSHO to determine compliance with 1910.1020.

5. OSHA 300 log – OAR 437-001-0700(12):

- a. For Oregon OSHA Form 300 recordkeeping purposes, both tuberculosis infections (positive TB skin test) and TB are recordable in the high risk setting. A positive skin test for tuberculosis, even on initial testing, except pre-assignment screening, is recordable on the OSHA 300 log because there is an assumption it is work-related, unless there is clear documentation that an outside exposure occurred.

Note: In this case, pre-assignment means the same as pre-employment and initial testing is the same as baseline testing.

- b. If the employee's tuberculosis infection which was entered on the Oregon OSHA 300 log progresses to TB during the five-year maintenance period, the original entry for the infection must be updated to reflect the new information. Because it is difficult to determine if TB resulted from the source indicated by the skin test conversion or from subsequent exposures, only one case should be entered to avoid double counting.
- c. A positive TB skin test provided within two weeks of employment does not have to be recorded on the OSHA 300 forms. However, the initial test must be performed prior to any potential workplace exposure within the initial two weeks of employment. (See pg. 4 of the CDC Guidelines)

M. EXPERT WITNESS:

The Standards and Technical Section will assist field offices in locating expert witnesses. Expert witnesses must be contacted before issuing citations.

1. In the event that a 654.010 citation is contested, proper expert witness support will be required. The expert must be prepared to address the following issues:
 - a. The risk to workers associated with the exposure

circumstances.

- b. Existence, feasibility, and utility of abatement measures.
 - c. Recognition of the hazard in the industry.
2. Expert witnesses may also be necessary in other cases, particularly those involving 1910.134.

**N. RECORDING
IN THE IMIS:**

A TB-related inspection is any health inspection (referral or complaint) conducted to investigate the presence or alleged presence of TB.

1. When a TB-related inspection is conducted, complete the OSHA-1 as for any inspection and enter the code “N 02 TB” in Item 42, Optional Information.

| Type | ID | Value |
|------|----|-------|
| N | 2 | TB |

2. When an OSHA-7 is completed and the complaint alleges the presence of TB hazards, enter the code “N 02 TB” in Item 46, Optional Information.
3. When an OSHA-90 is completed and the referral alleges the presence of TB hazards, enter the code “N 02 TB” in Item, 26, Optional Information.

O. RESERVED.

**P. PRE-CITATION
REVIEW:**

The Field Health Enforcement Manager must review all citations issued according to this directive. The manager reviews for consistency with these procedures and establishes expert witness support.

APPENDIX A

Smoke-Trail Testing Method for Negative Pressure Isolation Room

Test method description:

One purpose of a negative pressure TB airborne infection isolation (AII) room is to prevent TB droplet nuclei from escaping the AII room and entering the corridor or other surrounding uncontaminated spaces. To check for negative room pressure, use smoke-trails to demonstrate that the pressure differential is inducing airflow from the corridor, through the crack at the bottom of the door (undercut) and into the AII room. When performing a smoke-trail test, follow these recommendations where applicable:

1. Test only with the AII room door shut. If not equipped with an anteroom, it is assumed that there will be a loss of space pressure control when the AII door is opened and closed. It is not necessary to demonstrate direction of airflow when the door is open.
2. If there is an anteroom, release smoke at the inner door undercut with both anteroom doors shut.
3. In addition to a pedestrian entry, some AII rooms are also accessed through a wider wheeled-bed stretcher door. Release smoke at all door entrances to AII rooms.
4. So that the smoke is not blown into the AII room, hold the smoke bottle/tube parallel to the door so the smoke is released perpendicular to the direction of airflow through the door undercut.
5. Position the smoke bottle/tube tight to the floor, centered in the middle of the door jamb and approximately 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. Minimize momentum imparted to the smoke by squeezing the bulb or bottle slowly. This will also help minimize the volume of smoke released.
8. Depending on the velocity of the air through the door undercut, the smoke plume will either stay disorganized or it will form a distinct streamline. In either case, the smoke will behave in one of three ways:
 - a. Go through the door undercut into the isolation room
 - b. Remain motionless
 - c. Blow back into the corridor.

Compliance with the intent of the CDC Guidelines for negative pressure requires that the smoke be drawn into the AII room through the door undercut.

9. Release smoke from the corridor side of the door only for occupied TB AII rooms. If the room is unoccupied, also release smoke inside the AII room (same position as in Step No. 5) to verify that released smoke remains contained in the AII room – smoke is being used as a surrogate for TB droplet nuclei.
10. If photography is performed or videotaping, it is recommended that a dark surface be placed on the floor to maximize contrast. Be aware that most auto-focusing cameras cannot focus on smoke.

Testing "as used" conditions:

Testing of negative pressure isolation rooms require that the test reflect "as-used" conditions. Consider the following use variables that may affect space pressurization and the performance of the negative pressure AII room:

1. Patient toilet rooms are mechanically exhausted to control odors. The position of the toilet room door may affect the pressure differential between the AII room and the corridor. Smoke-trail 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 will adversely affect the performance of a negative pressure AII room. If the AII room is equipped with an operable window, perform smoke-trail tests with the window open and the window closed.
3. There may be corridor doors that isolate the respiratory ward or wing from the rest of the facility. These corridor doors are provided in the initial design to facilitate space pressurization schemes or building, life, safety codes. Direct communication 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 AII room. Perform AII room smoke-trail testing with those corridor doors in their "as-used" position, which is either normally open or normally closed.
4. AII rooms may be equipped with auxiliary, fan-powered, recirculating, stand alone HEPA filtration or UV units. These units must be running when smoke-trail tests are performed.
5. Do not restrict corridor foot traffic while performing smoke-trail tests.
6. Negative pressure is accomplished by exhausting more air than is supplied to the AII room. Some HVAC systems employ variable air volume (VAV) supply air and sometimes VAV exhaust air. By varying the supply air delivered to the space to satisfy thermal requirements, these VAV systems can adversely impact the performance of a negative pressure AII room. If the AII room or the corridor is served by a VAV system, you should perform the smoke test twice. Perform the smoke test with the zone thermostat thermally satisfied and again with the zone thermostat thermally unsatisfied, thus stimulating the full volumetric flowrate range of the VAV system serving the area being tested.

Smoke:

Most smoke tubes, bottles, and sticks use titanium chloride (TiCl_4) to produce a visible fume. There is no Oregon OSHA PEL or ACGIH TLV for this chemical although it is a recognized inhalation irritant. Healthcare professionals are concerned about releasing TiCl_4 around pulmonary patients. The smoke released at the door undercut makes only one pass through the isolation room and is exhausted directly outside. All room air is typically not recirculated.

Room air cleaners in the room should be operating. People using smoke tubes should avoid inhaling the smoke, because direct inhalation of high concentrations of the smoke can be irritating. Nonirritating smoke tubes are available and should nevertheless be utilized whenever possible. Provide material Safety data sheets and hazard communication training to people who use smoke tubes.

Appendix B

TB Infection-Control Program

Every healthcare setting should have a TB infection control plan that is part of an overall infection control program. The specific details of the TB infection control program will differ, depending on whether patients with suspected or confirmed TB might be encountered in the setting or whether patients with suspected or confirmed TB will be transferred to another healthcare setting.

Healthcare-associated transmission of *M. tuberculosis* has been linked to close contact of people with TB during aerosol-generating or aerosol-producing procedures, including bronchoscopy, endotracheal intubation, suctioning, other respiratory procedures, open abscess irrigation, autopsy, sputum induction, and aerosol treatments that induce coughing.

Of the reported TB outbreaks in healthcare settings, multiple outbreaks involved transmission of MDR TB strains to patients and HCWs. The majority of the patients and certain HCWs were HIV infected, and progression to TB and MDR TB was rapid. Factors contributing to these outbreaks included delayed diagnosis of TB, delayed initiation and inadequate airborne precautions, lapses in AII practices and precautions for cough-inducing and aerosol-generating procedures, and lack of adequate respiratory protection. Multiple studies suggest that the decline in healthcare-associated transmission observed in specific institutions is associated with the rigorous implementation of infection control measures. Because various interventions were implemented simultaneously, the effectiveness of each intervention could not be determined.

After the release of the 1994 CDC infection control guidelines, increased implementation of recommended infection control measures occurred and was documented in multiple national surveys. In a survey of approximately 1,000 hospitals, a TST program was present in nearly all sites, and 70% reported having an AII room. Other surveys have documented improvement in the proportion of AII rooms meeting CDC criteria and proportion of HCWs using CDC-recommended respiratory protection and receiving serial TST. A survey of New York City hospitals with high caseloads of TB indicated 1) a decrease in the time that patients with TB spent in EDs before being transferred to a hospital room, 2) an increase in the proportion of patients initially placed in AII rooms, 3) an increase in the proportion of patients started on recommended antituberculosis treatment and reported to the local or state health department, and 4) an increase in the use of recommended respiratory protection and environmental controls. Reports of increased implementation of recommended TB infection controls combined with decreased reports of outbreaks of TB in healthcare settings suggest that the recommended controls are effective in reducing and preventing healthcare-associated transmission of *M. tuberculosis*.

Less information is available regarding the implementation of CDC-recommended TB infection control measures in settings other than hospitals. One study identified major barriers to implementation that contribute to the costs of a TST program in health departments and hospitals, including personnel costs, HCWs' time off from work for TST administration and reading, and training and education of HCWs. Outbreaks have

occurred in outpatient settings, i.e., private physicians' offices and pediatric settings, where the guidelines were not followed. CDC-recommended TB infection control measures are implemented in correctional facilities, and variations of control measures could relate to resources, expertise, and oversight.

Fundamentals of TB Infection Control

One of the most critical risks for healthcare-associated transmission of *M. tuberculosis* in healthcare settings is from patients with unrecognized TB or MDR TB who are not promptly handled with appropriate airborne precautions or who are moved from an AII room too soon.. In the United States, the problem of MDR TB, which was amplified by healthcare-associated transmission, has been substantially reduced by using standardized antituberculosis treatment regimens in the initial phase of therapy, rapid drug-susceptibility testing, directly observed therapy (DOT), and improved infection control practices. DOT is an adherence-enhancing strategy in which an HCW or other specially trained health professional watches a patient swallow each dose of medication and records the dates that the administration was observed. DOT is the standard of care for all patients with TB and should be used for all doses during the course of therapy for TB and for LTBI, whenever feasible.

➤ Administrative controls

The first and most important level of TB controls is the use of administrative measures to reduce the risk for exposure to people who might have TB. Administrative controls consist of the following activities:

- Assigning responsibility for TB infection control in the setting.
- Conducting a TB risk assessment of the setting.
- Developing and instituting a written TB infection control plan to ensure prompt detection, airborne precautions, and treatment of people who have suspected or confirmed TB.
- Ensuring the timely availability of recommended laboratory processing, testing, and reporting of results to the ordering physician and infection control team.
- Implementing effective work practices for managing patients with suspected or confirmed TB.
- Ensuring proper cleaning, sterilizing, or disinfecting potentially contaminated equipment – usually endoscopes.
- Training and educating HCWs regarding TB, with specific focus on prevention, transmission, and symptoms.
- Screening and evaluating HCWs who are at risk for TB or who might be exposed to *M. tuberculosis* (TB screening program).
- Applying epidemiologic-based prevention principles, including the use of setting-related infection control data.

- Using signage advising respiratory hygiene and cough etiquette.
 - Coordinating efforts with the local or state health department.
- Environmental controls
- The second level of the hierarchy is using environmental controls to prevent the spread and reduce the concentration of infectious droplet nuclei in ambient air.
- Primary environmental controls consist of controlling the source of infection by using local exhaust ventilation, such as hoods, tents, or booths, and diluting and removing contaminated air by using general ventilation.
 - Secondary environmental controls consist of controlling the airflow to prevent contamination of air in areas adjacent to the source (All rooms) and cleaning the air by using high efficiency particulate air (HEPA), filtration, or UVGI.
- Respiratory-protection controls
- The first two control levels minimize the number of areas in which exposure to *M. tuberculosis* might occur; therefore, minimizing the number of people exposed. These control levels also reduce, but do not eliminate, the risk for exposure in the limited areas in which exposure can still occur. Because people entering these areas might be exposed to *M. tuberculosis*, the third level of the hierarchy is using respiratory protective equipment in situations that pose a high risk for exposure. Use of respiratory protection can further reduce risk for exposure of HCWs to infectious droplet nuclei that have been expelled into the air from a patient with infectious TB. The following measures can be taken to reduce the risk for exposure:
- Implementing a respiratory protection program.
 - Training HCWs on respiratory protection.
 - Training patients on respiratory hygiene and cough etiquette procedures.