



# CLINICS

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Patients who are at high risk for TB often receive care at public health and community clinics prior to diagnosis and treatment. Clinic funding does not generally allow for facility renovation or installation of special ventilation. Furthermore, clinic staffing does not always include experienced infection control, occupational health, or mechanical engineering personnel, which often places clinic staff and other patients at increased risk of exposure to TB.

To help reduce the risk of exposure to TB, clinics should have a TB infection control plan (ICP) in place that is part of the overall infection control program. This section of the manual describes the problems faced by clinics, how to develop and maintain an effective TB ICP, and how to reduce the risk of TB exposure for clinic staff.

## **TB Infection Control Plans (ICP)**

Employers who fall within the scope of federal or state OSHA TB compliance requirements must establish and comply with an effective written TB ICP. The TB ICP must contain information about how that facility:

- Defines employees who are at risk of occupational TB exposure
- Identifies suspected or confirmed TB cases
- Isolates or controls exposures when a suspected or confirmed infectious TB patient is identified
- Minimizes employee exposure to TB
- Alerts employees to hazards
- Screens employees for TB
- Conducts follow-up of employees exposed to TB
- Protects employees during high-risk procedures
- Uses environmental controls to reduce the likelihood of TB exposure
- Maintains environmental controls
- Uses respirators (a written respiratory protection program is also required)
- Provides employees with TB training

All of the above information must be specific to the facility and available to any employee who requests it. The effectiveness of the ICP should be evaluated annually and following any occupationally-acquired employee TB infection.

## Meeting Regulatory Requirements

Efforts have been made to ensure that this TB ICP section of the manual includes applicable recommendations from the CDC and meets existing standards set by regulatory agencies such as OSHA and Cal/OSHA. Although this manual addresses the most important issues in clinic TB control efforts, it may not address every issue of interest to all regulatory agencies.

Because regulations vary from county to county and from state to state, each facility should review its local and state regulations before finalizing its TB ICP. Each facility must also ensure that the final ICP accurately reflects current practices and the environmental controls of its clinic building.

## Facility Risk Assessment

Assessing your facility's risk for *M. tuberculosis* transmission is the first step in developing an ICP. The CDC and OSHA recognize that this risk is not equal in all facilities. The risk level will vary depending on the population served, the type of building, the procedures performed, community/facility prevalence, and other factors. Clinics may be located in buildings converted from business offices and grocery stores, or in new structures built specifically for the delivery of healthcare services. The TB risk level of the population treated and the community itself will vary. Some clinics perform high-risk procedures, such as sputum induction and bronchoscopy, and some do not. All these factors affect the likelihood of *M. tuberculosis* transmission in a facility, and therefore, the level of TB control intervention required. The frequency of screening HCWs for TB, use of respirators, and facility use of environmental controls such as AIIRs, will influence the risk level of the facility.

## Determining the Facility's Risk

Assessing the risk level of your facility will help determine the level of TB control needed in the following areas:

- Employee TB screening
- Environmental controls
- Respiratory protection

Guidance on performing a complete risk assessment can be found on pages 9-10 and the revised version of Appendix B: TB Risk Assessment Worksheet, of the CDC Guidelines. The CDC notes that a medium-risk category is warranted if drug-resistant TB has occurred in the community or facility, or if there is a relatively high prevalence of HIV infection among patients or HCWs. The CDC Guidelines also recommend that facilities be classified as medium-risk if cough-inducing procedures (e.g., sputum induction, bronchoscopy, and administration of aerosolized medications) are performed on patients who may have TB disease. Read the entire TB ICP and review the available options. If it is determined that a facility is medium-risk, select options that provide the greatest protection to staff and patients. Low-risk facilities are free to select these more protective options, if desired.

Please consult Appendix B (revised version) of the CDC guidelines to determine the risk level for your facility. Use the worksheet on page 53 of this manual to identify who is responsible for the various controls in the TB ICP.

*Low-risk facilities are free to select these more protective options, if desired.*

TABLE 3.

Excerpt from CDC guidelines Appendix C:

**Risk classifications for health-care settings that serve communities with high incidence of tuberculosis (TB) and recommended frequency of screening for *Mycobacterium tuberculosis* infection among health-care workers (HCWs)\***

Setting	Risk classification <sup>†</sup>		Potential ongoing transmission <sup>§</sup>
	Low risk	Medium risk	
Inpatient <200 beds	<3 TB patients/year	≥3 TB patients/year	Evidence of ongoing <i>M. tuberculosis</i> transmission, regardless of setting
Inpatient ≥200 beds	<6 TB patients/year	≥6 TB patients/year	
Outpatient; and nontraditional facility-based	<3 TB patients/year	≥3 TB patients/year	
TB treatment facilities	Settings in which <ul style="list-style-type: none"> <li>• persons who will be treated have been demonstrated to have latent TB infection (LTBI) and not TB disease</li> <li>• a system is in place to promptly detect and triage persons who have signs or symptoms of TB disease to a setting in which persons with TB disease are treated</li> <li>• no cough-inducing or aerosol-generating procedures are performed</li> </ul>	Settings in which <ul style="list-style-type: none"> <li>• persons with TB disease are encountered</li> <li>• criteria for low risk is not otherwise met</li> </ul>	
Laboratories	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are not manipulated	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are manipulated	
<b>Recommendations for Screening Frequency</b>			
Baseline two-step TST or one BAMT <sup>¶</sup>	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire
Serial TST or BAMT screening of HCWs	No**	Every 12 months <sup>††</sup>	As needed in the investigation of potential ongoing transmission <sup>§§</sup>
TST or BAMT for HCWs upon unprotected exposure to <i>M. tuberculosis</i>	Perform a contact investigation (i.e., administer one TST as soon as possible at the time of exposure, and, if the TST result is negative, place another TST 8–10 weeks after the end of exposure to <i>M. tuberculosis</i> ) <sup>¶¶</sup>		

\* Health-care workers (HCWs) refers to all paid and unpaid persons working in health-care settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with TB disease.

<sup>†</sup> Settings that serve communities with a high incidence of TB disease or that treat populations at high risk (e.g., those with human immunodeficiency virus infection or other immunocompromising conditions) or that treat patients with drug-resistant TB disease might need to be classified as medium risk, even if they meet the low-risk criteria.

<sup>§</sup> A classification of potential ongoing transmission should be applied to a specific group of HCWs or to a specific area of the health-care setting in which evidence of ongoing transmission is apparent, if such a group or area can be identified. Otherwise, a classification of potential ongoing transmission should be applied to the entire setting. This classification should be temporary and warrants immediate investigation and corrective steps after a determination has been made that ongoing transmission has ceased. The setting should be reclassified as medium risk, and the recommended timeframe for this medium risk classification is at least 1 year.

<sup>¶</sup> All HCWs should have a baseline two-step tuberculin skin test (TST) or one blood assay for *M. tuberculosis* (BAMT) result at each new health-care setting, even if the setting is determined to be low risk. In certain settings, a choice might be made to not perform baseline TB screening or serial TB screening for HCWs who 1) will never be in contact with or have shared air space with patients who have TB disease (e.g., telephone operators who work in a separate building from patients) or 2) will never be in contact with clinical specimens that might contain *M. tuberculosis*. Establishment of a reliable baseline result can be beneficial if subsequent screening is needed after an unexpected exposure to *M. tuberculosis*.

\*\* HCWs whose duties do not include contact with patients or TB specimens do not need to be included in the serial TB screening program.

<sup>††</sup> The frequency of testing for infection with *M. tuberculosis* will be determined by the risk assessment for the setting.

<sup>§§</sup> During an investigation of potential ongoing transmission of *M. tuberculosis*, testing for *M. tuberculosis* infection should be performed every 8–10 weeks until lapses in infection controls have been corrected and no further evidence of ongoing transmission is apparent.

<sup>¶¶</sup> Procedures for contact investigations should not be confused with two-step TST, which is used for newly hired HCWs.

# Responsibility

Use the following worksheet to identify who is responsible for the various controls in the TB ICP. In the first column, insert the appropriate name, position or committee responsible for that control.

POSITION / COMMITTEE RESPONSIBLE	RESPONSIBILITY
	Ensure full compliance with the provisions of this TB ICP
	Perform risk assessment annually; review and revise TB ICP as needed
	Review and approve facility risk assessment and TB ICP
	Educate and document facility-wide TB education
	Monitor compliance with TB ICP and report compliance issues for resolution
	Develop and implement TB screening program for employees, physicians, and volunteers
	Monitor and maintain environmental controls
All Employees	Comply with all elements of the TB ICP, including attending education sessions, obtaining required screening, using respirators when indicated, using safe work practices, and reporting all TB exposures
	Administer and maintain the Respiratory Protection Program

**Note:** Delete the last row if your classification is low-risk, all patients with TB disease are immediately transferred to another location, and you elect to not use respirators.

# Employee Categories at Risk

All employees working in the clinic who share air with patients who may have infectious TB are considered to be at risk for TB exposure. Review the following list of at risk employee categories and determine which categories apply to your facility:

- Counselors and interviewers
- Engineering and building maintenance staff
- Housekeeping personnel who work in the clinic
- Laboratory staff
- Medical records or clerical staff, if work area is within clinic or is ventilated by clinic ventilation system
- Nurses and medical assistants
- Patient-care personnel who provide directly observed therapy (DOT) or visit patients in their homes
- Physicians
- Radiology staff
- Registration staff
- Security guards who spend time in clinic
- Volunteers who will spend more than 6-8 hours in the setting cumulatively working with persons who may have TB

## Registry and Contract Personnel

- Clinic management should ensure that registry and contract personnel in any of the above categories have received TB education, TB screening, and respirator fit testing (if needed) from their employer
- Clinic supervisors will provide these employees with any clinic-specific TB control information necessary for them to safely perform their work
- Registry or other employer, and the employee, should be notified in writing of all exposures

## Administrative Controls

This TB ICP is based on a hierarchy of three levels of controls: administrative controls, environmental controls, and respiratory protection. Administrative controls, the first level of the hierarchy, are intended to reduce the risk or exposure to persons with infectious TB.

Administrative controls include:

- Assigning responsibility for the TB ICP
- Conducting a TB risk assessment of the setting
- Implementing work practice controls
- Training, educating, and counseling employees about TB
- Screening employees for TB infection and disease
- Developing and implementing TB control policies and procedures to ensure prompt identification, isolation, evaluation, and treatment of persons likely to have TB

# Work Practice Controls

## Definition of a Suspected Infectious TB Patient

An individual will be suspected of having infectious TB (unless the individual's condition has been medically determined to result from a cause other than TB) if it is determined that the individual:

- Is known, or with reasonable diligence should be known, to have TB infection and has signs and symptoms of pulmonary or laryngeal TB, or
- Has a positive acid-fast bacilli (AFB) sputum smear, or
- Has a persistent cough lasting 3 or more weeks and one or more symptoms of TB disease (e.g., fever, night sweats, fatigue, unexplained weight loss, bloody sputum [hemoptysis]), or
- Has been started on antituberculosis medications for clinical suspicion of active pulmonary or laryngeal TB, but has completed less than 2 weeks of treatment or has not demonstrated clinical response.

Your clinic may serve persons with additional symptoms or risk factors including HIV infection, homelessness, alcoholism or drug abuse, poor nutrition, or medical conditions that increase the risk of progression from LTBI to TB disease. A definition that is applicable to your clinic should be included in your TB ICP.

## Early Identification

Efforts to identify suspected or confirmed infectious TB patients will begin as soon as the patient enters the clinic. All clinic personnel are encouraged to identify patients who are coughing. Registration personnel are encouraged to ask simple questions such as, "How long have you had that cough?" or "Do you have any symptoms other than your cough?" Patients with coughs lasting more than 3 weeks, or who have other signs and symptoms of TB will be immediately referred to triage personnel.

Triage personnel can use a written questionnaire to assist in the early identification of persons with suspected or known infectious TB. Rapid identification of these patients will enable staff to mask or isolate them as necessary. See page 146 and page 155 for tools that you can use for this identification process.

The TB ICP will document the risk level and/or practice at your facility. Choose one of the following paragraphs for this documentation:

- This clinic has been assessed as a **low-risk facility** for *M. tuberculosis* transmission. Patients will not be screened for TB unless they have signs or symptoms of TB.
- This clinic has been assessed as a **medium-risk facility** for *M. tuberculosis* transmission. Any patient with symptoms of TB or known HIV infection will be screened for TB.

If the risk level of the clinic is ever determined to be **potential ongoing transmission** of *M. tuberculosis*, all patients presenting to the clinic for service will be screened for TB symptoms and risk factors. This is a temporary risk classification that requires immediate investigation and corrective steps. After determination is made that ongoing transmission has ceased, the clinic will be reclassified as medium-risk and maintain that classification (medium-risk) for 1 year.

## Patient Respiratory Protection

Individuals with suspected or known infectious TB should wear a surgical mask when not in an AIIR or a local exhaust ventilation (LEV) enclosure. The purpose of the mask is to block aerosols produced by coughing, talking, and breathing. Patients will be monitored to ensure compliance, and masks will be changed when damp.

## Isolating Persons with Suspected Infectious TB

Masked patients will be escorted to a private waiting area, exam room, or other room to prevent transmission and avoid embarrassment and concern. The TB ICP should identify which rooms have been designated for isolation of persons with suspected or known infectious TB.

The following are examples of paragraphs you can include:

- Room(s) \_\_\_\_\_ has/have been designated for isolation of persons with suspected or known infectious TB. This room is under negative pressure; exhausts directly outside, away from air intake vents, operable windows, and doors; and has at least \_\_\_\_\_ ACH. The room door will be closed when occupied by a person with suspected or known infectious TB. A sign will be placed to alert staff to use proper precautions. The sign will read: “STOP, CHECK WITH NURSE BEFORE ENTERING, WEAR RESPIRATOR TO PROTECT YOUR LUNGS.” A sign will be placed on the door to indicate when the room will be safe for use after the patient leaves

**Note:** *Twelve (12) ACH is the minimum ventilation rate recommended by the CDC for new or renovated AIIRs, and where portable HEPA filtration units are used. CDC allows 6 ACH for existing AIIRs, but recommends that this be increased to 12 ACH “where feasible.” In general, 12 ACH is usually feasible. It should be noted that, even for existing rooms, 6 ACH may not satisfy local requirements. See Appendix G on page 150 for a worksheet to calculate room clearance time. See Appendix L on page 157 for sample room signs*

- Room(s) \_\_\_\_\_ has/have been designated for segregation of persons with suspected or known infectious TB. These rooms have been selected because they are located away from immunocompromised patients and young children. Since these rooms do not meet the CDC criteria for AIIRs, patients will be masked and supervised for compliance with masking. The room door will be closed when occupied by a person with suspected or known infectious TB. A sign will be placed on the door that reads: “PATIENT UNDER RESPIRATORY PRECAUTIONS.” A small portable HEPA filter will run in the room when it is occupied by a person with suspected or known infectious TB. The HEPA unit will run for \_\_\_\_\_ minutes after the patient leaves. A sign will be placed on the door to indicate when the room will be safe for use after the patient leaves

In addition, the TB ICP should identify where warning signs are stored. This location should be close to the AIIR and accessible to all employees.

## Fast Tracking

A person with suspected or known infectious TB in need of a medical test or procedure will be accompanied to other departments and will not wait in occupied waiting rooms. Communicating with the receiving department prior to the patient’s arrival will minimize delays.

For example, a suspected infectious TB patient who needs a chest x-ray will be masked and escorted to the radiology department. The escort is provided to ensure that the patient does not remove the mask or get lost. The receiving department will be notified prior

to patient arrival. Staff will be ready to perform the x-ray immediately to avoid possible exposure of other patients and staff.

Whenever possible, tests such as electrocardiograms and specimen collection for laboratory analysis will be performed where the isolated or segregated patient is located, further reducing the risk of transmission to other patients and staff.

### **Delay of High-Risk Procedures**

High-risk (cough-inducing) procedures, which are not immediately required for diagnosis or treatment, will be delayed until the person with suspected or confirmed infectious TB is no longer contagious.

### **Covering Coughs**

Tissue dispensers are placed within reach of patients throughout the facility. Signs are placed in all waiting areas to remind patients to “Cover Your Cough” (see Appendix L on page 157 for sample signs).

Nursing and registration staff have been trained, and are encouraged, to provide tissues and remind patients to cover coughs.

### **Transfer of Suspected or Confirmed Infectious TB Patients**

If your facility needs to transfer suspected or confirmed infectious TB patients, include a section in the TB ICP on how to handle those patients. For example:

This facility does not have an AIIR. All patients with suspected or known infectious TB are transferred to \_\_\_\_\_, a facility with AIIR(s).

While awaiting transfer, persons with suspected or known infectious TB will wear surgical masks and will remain isolated in room \_\_\_\_\_, which has been designated for this purpose.

## **Employee Education**

TB prevention training for employees is provided as mandated by OSHA and recommended by the CDC. Training is offered to employees upon employment during regular work hours and annually thereafter.

The employee signs a training record sheet at the end of the session to acknowledge understanding of information described in the learning objectives. See Appendix I “TB Infection Control Training Record” on page 154 for a sample sign-off sheet.

The following topics are included in employee TB education:

- Where to get a copy of the TB ICP if desired
- Groups at risk for occupational TB, especially immunocompromised workers
- Modes of *M. tuberculosis* transmission
- Symptoms of TB
- TB screening and treatment for LTBI
- MDR TB
- Procedure for isolating persons with suspected or known infectious TB

*Whenever possible, tests such as electrocardiograms and specimen collection for laboratory analysis will be performed where the isolated or segregated patient is located, further reducing the risk of transmission to other patients and staff.*

- Employer and employee responsibilities under the TB ICP
- Use and limitations of methods that will prevent TB transmission, including administrative and work-practice controls, environmental controls, and respiratory protection
- Reuse and disposal of respirators

The educational session includes an opportunity for interactive questions and answers with the instructor.

### **Employees Required to Attend TB Prevention Education**

Identify the persons who work in increased-risk environments and are required to attend TB prevention education. If you choose to educate all employees, specify that in the TB ICP.

All employees listed on page 54 who may work with persons with suspected or confirmed TB should be included in the TB education and training.

### **Employees Who Are Not Required to Attend TB Prevention Education**

Identify the individuals who are not mandated to attend TB education, as they are not at increased risk for *M. tuberculosis* transmission:

- Outdoor security guards
- Equipment repair personnel who primarily work off-site
- Clerical staff who work off-site or in a separately ventilated clinic area

If you choose to educate all employees, the identification of these employees will not be needed. If some of these categories do not exist in your facility, do not include them in your TB ICP.

### **Educational Record Maintenance**

Educational records will include the class topic, name and qualifications of the instructor, employee name, position, department, and date and time of educational program. To document that the employee attended the training session, the employee must sign the training record sheet. Records will be maintained for 3 years.

## **Pre-placement and Periodic Employee Screening**

All employees, physicians, and volunteers who have potential for exposure to *M. tuberculosis* will be screened for TB at hire, and at least annually thereafter by TST or IGRA, if indicated by the settings' TB IC policies or TB risk classification, and complete a TB symptom review questionnaire. For a sample HCW screening questionnaire, please see Appendix E on page 147. Contract employees and students must provide proof of TB screening that meets this facility's requirements prior to assignment. The clinic's policies will specify which method of TB testing will be used in the setting (TST or IGRA). Follow the content provided here that is specific for the selected testing method. Either method is acceptable for diagnosing LTBI. However, the IGRA method requires different equipment, laboratory, and courier service to ensure prompt and proper processing of the blood specimens.

## TB Symptom Screen

All employees, physicians, and volunteers will be screened at hire and at least annually for TB symptoms such as:

- Cough lasting more than 3 weeks
- Fever
- Night sweats
- Fatigue
- Unexplained weight loss
- Hemoptysis (bloody sputum).

TB symptom screen will be repeated annually by all employees regardless of their TST status.

## Symptomatic Employees

Any employee, physician, or volunteer with a persistent cough, especially in the presence of other signs or symptoms of TB, will be evaluated promptly for TB. The individual will not return to work until the following criteria are met:

- TB disease is ruled out based on physical exam, chest x-ray, and bacteriology (if indicated); or
- TB disease is diagnosed and treated, and the individual is determined to be non-infectious as defined below:
  - Had three negative AFB sputum smears obtained 8-24 hours apart, with at least one being an early morning specimen; and
  - Responded to antituberculosis treatment that will probably be effective, based on susceptibility results; and
  - Had been determined to be noninfectious by a physician knowledgeable and experienced in managing TB disease.

## Interferon Gamma Release Assay (IGRA)

IGRA is the term used to refer to the blood test that detects infection with *M. tuberculosis*. A more general term for these tests is Blood Assay for Mycobacterium Tuberculosis (BAMT). In this manual we will use IGRA to refer to all blood tests currently used to diagnose TB infection in Europe and the United States. QuantiFERON®-TB Gold (QFT-G) is the IGRA that was approved by the FDA in 2005 and is currently recommended by CDC as a diagnostic test for TB infection. QFT-G measures the T-cell immune responses to two *M. tuberculosis* proteins that are not present in any BCG vaccine strain nor in the majority of nontuberculous mycobacteria (NTM). Therefore, QFT-G is a more accurate test when compared to the TB skin test because it is much less likely to be falsely positive in individuals who have received BCG vaccinations or are infected with most other environmental mycobacteria.

The results of IGRAs are automated and reported by laboratory technology. Unlike the TST, IGRAs do not involve reading or interpretation by health staff. This means results are more consistent and less prone to errors made in placing and reading a skin test. A positive QFT-G result occurs when interferon gamma concentrations reach a designated threshold. A positive result suggests that *M. tuberculosis* infection is likely; a negative result suggests that TB infection is not likely; an indeterminate result suggests that the QFT-G result cannot be interpreted. For a person with an indeterminate IGRA result, healthcare

*IGRAs are a new test and it is still unclear how to use prior TST information when interpreting the new IGRA result, expert advice may be needed in some situations.*

providers should consult a physician who is knowledgeable and experienced in managing TB disease.

When using IGRAs in healthcare workers (HCWs) or other workers who need annual testing, only a single step test is needed at baseline, unlike the two-step testing used in skin testing. If the test changes from a negative to a positive result within a 2-year period, the person is considered a “converter” or newly infected. IGRAs are a new test and it is still unclear how to use prior TST information when interpreting the new IGRA result and expert advice may be needed in some situations. In addition to a positive or a negative result, the test may be reported as “indeterminate.” An indeterminate result means that the test cannot be used to determine infection because of a lack of appropriate responses to the controls in the test. In these situations, the IGRA can be repeated or a TST can be used to avoid getting another indeterminate result. As with the TST, QFT-G results and their interpretation should be considered in conjunction with other epidemiological, historical, physical, and diagnostic findings.

More immunoassays are being developed that should be useful in the diagnosis of TB infection. Future test methods using FDA-approved products, in combination with CDC issued recommendations, may provide additional diagnostic options. CDC will periodically publish guidelines as alternate methods become available.

### **Testing Health-care Workers for TB**

All employees, physicians, and volunteers who have unknown or undocumented previous TST or IGRA results will have a TST or IGRA administered and read prior to starting employment.

### **Mantoux Tuberculin Skin Test (TST)**

Identify the name(s) and job title(s) of the practitioner who will place the TST and who will read the TST result after 48-72 hours. Employees may not read their own TST results.

### **Two-Step Skin Testing**

Two-step testing is used to detect individuals with TB infection acquired in the remote past who may now have diminished skin test reactivity. This procedure reduces the likelihood that a boosted reaction will later be interpreted as new infection in employees who are periodically tested.

- Two-step testing is performed on all new employees who do not have written documentation of a negative TST result in the preceding 12 months and have an initial negative TST result at the time of employment
- The second TST is placed 1-3 weeks after the initial test result is read. Employees who have a negative reaction to the first test and a negative TB symptom screen may start work before the second test is placed. Any employee with a persistent cough (more than 3 weeks), especially in the presence of other signs or symptoms compatible with TB, should be excluded from the workplace and promptly evaluated for TB
- Asymptomatic employees with a positive (boosted) reaction to the second TST are considered previously infected. The employee will be given a baseline chest x-ray and referred for consideration of treatment for TB infection

## Past Positive TST

Employees, physicians, and volunteers who have written documentation of a previous positive TST result are required to have a baseline chest x-ray at hire or provide written documentation of a normal chest x-ray taken no more than 12 months prior to hire. The chest x-ray will be repeated only if the employee develops signs or symptoms of TB or when the attending physician decides a repeat chest x-ray is needed.

Screening is conducted, at least annually, via a TB symptom review questionnaire. The symptom review form will be completed whenever a TST would be required of an employee with a negative TST result. If the symptom screen reveals signs or symptoms of TB, the employee will be excluded from the workplace. A new chest x-ray and physical assessment is then required.

## BCG Vaccination

A history of previous vaccination with Bacille Calmette-Guerin (BCG) is not a contraindication for having TSTs. Criteria for placing and interpreting TST results are unchanged.

TABLE 4.

### Definition of a Positive TST Result for HCWs

TST results are always recorded in millimeters (mm) of induration measured across arm, not simply as positive or negative. Erythema (redness) without induration should not be measured. A TST result with no induration is recorded as 0 mm.

5 mm or greater is considered positive in:	10 mm or greater is considered positive in:	15 mm or greater is considered positive in:
<ul style="list-style-type: none"> <li>• Persons with HIV infection</li> <li>• Recent contacts of a person with TB</li> <li>• Organ transplant recipients</li> <li>• Persons with other immunosuppressing conditions (e.g., receiving &gt;15 mg/day of prednisone for &gt;1 month)</li> <li>• Persons with fibrotic changes on chest x-rays consistent with previous TB disease</li> </ul>	<ul style="list-style-type: none"> <li>• Persons with medical conditions (e.g., diabetes, chronic renal failure, silicosis, etc.) that increase the risk of progression to TB disease</li> <li>• Persons who use intravenous drugs</li> <li>• Foreign-born persons from areas where TB is common who have immigrated to the US within the past 5 years</li> <li>• All employees of healthcare, correctional, homeless shelter, long term care, hospice, AIDS residential care (where TB patients receive care), and mycobacteriology laboratory settings</li> </ul>	<ul style="list-style-type: none"> <li>• All persons with no known risk factors (in some states, including California, 10 mm is the cutoff for all persons without risk factors)</li> <li>• HCWs with no known risk factors who work in facilities where the risk of TB exposure is very low</li> </ul>

## TST Conversion

A TST conversion is defined as an increase of at least 10 mm in the size of induration from less than 10 mm to 10 mm or greater within a 2-year period.

**Note:** *the CDC states, "For HCWs who are at low risk (e.g., those from low incidence settings), a baseline result of >15mm of induration (instead of >10mm) might possibly be the cut point."*

## Frequency and Timing

All clinic employees who work in areas where air may be shared with persons with suspected or known infectious TB must be screened for TB at least annually.

Include one of the following frequency options based on your facility risk assessment:

- This clinic has been assessed using a risk assessment tool and is classified as a **low-risk facility**. No additional TB screening is necessary unless unprotected exposure to an infectious TB patient occurs
- This clinic has been assessed using a risk assessment tool and is classified as a **medium-risk facility**. Employees will be screened for TB annually, on the anniversary of their hire dates, and following any unprotected exposure to an infectious TB patient.

If the clinic has been assessed as having evidence of **potential ongoing *M. tuberculosis* transmission**, employees will be screened for TB every 8-10 weeks until lapses in infection control have been corrected and there is no evidence of ongoing transmission. The clinic will then be reclassified as medium-risk and maintain that classification (medium-risk) for 1 year.

## More Frequent TB Screening for Increased Risk Employee Categories

If your facility overall is categorized as low-risk, but some employees are at increased risk for TB exposure, you may selectively increase the frequency of their TB screening. Identify the employee and physician categories that are designated at increased risk for TB exposure and screen them for TB annually.

Volunteers will not be placed in high-risk areas or participate in high-risk procedures.

## Evaluation of TST or IGRA Conversion

Any employee, physician, or volunteer with a TST or IGRA conversion or newly positive TST or IGRA result will have a chest x-ray within 1 week. Identify by name the clinic physician who will evaluate the chest x-ray. Alternately, the employee's private physician can evaluate the x-ray if preferred by the employee. Symptomatic employees will be excluded from work until cleared by a qualified physician with expertise in TB diagnosis and treatment.

## Employee with Suspected Infectious TB

If the symptom-screen, history, physical examination, or chest x-ray is consistent with TB disease, the worker will be excluded from the workplace until:

- A qualified physician rules out TB disease based on physical exam, chest x-ray, and bacteriology; or
- TB disease is diagnosed, treated, and the individual is determined to be non-infectious as defined above under 'Symptomatic Employees'

## TB Screening Record Maintenance

All employees, physicians, and volunteers will receive a copy of their TST results and interpretations. The following statement is included on the test result sheet, "HIV infection and other medical conditions may cause a TST result to be negative even when TB infection is present." The facility's copy of the TST form is maintained in the employee's confi-

dential health file. Records will be maintained for the duration of employment plus 30 years. Identify the person by position or title who will maintain an aggregate log of TSTs.

All employee TST conversions and confirmed TB cases will be recorded on the OSHA 300 Log unless substantiated as community-acquired.

### Facility TST or IGRA Conversion Rates

Identify how the TST or IGRA conversion rates are determined for your facility. Use one of the following paragraphs:

- The facility TST or IGRA conversion rate is calculated every 12 months to assess the level of occupational risk. The calculation is as follows:

$$\frac{\text{Total number of staff (except new hires) with newly positive TST or IGRA results/year}}{\text{Total number of staff (except new hires) who had TSTs applied and read/year or IGRAs completed/year}} \times 100 = \text{Conversion Rate}$$

- Facility TST or IGRA conversion rates are not calculated because a small number of employees receive TSTs or IGRAs. An epidemiological investigation will be conducted following any employee TST or IGRA conversion.

Determine and identify the appropriate committee or group (Infection Control Committee, Administration, Safety Committee, TB control staff) who will interpret the TST or IGRA conversion data. The committee will identify factors that could have contributed to transmission and infection, and recommend implementation of appropriate preventive measures.

### Compliance with TB Screening

Compliance with the TB screening program and post-exposure follow-up is mandatory for all employees, physicians, and volunteers. Identify the appropriate department or individual (department manager, employee health, human resources) who will notify the staff when screening is due. Employees will have 30 days to complete the screening process. Failure to comply will result in disciplinary action up to, and including, removal from the work schedule.

## Employee Exposure and Follow-up

Clinic employees may be inadvertently exposed to TB during the course of their work.

### Exposure Definition

An employee is considered exposed when the employee has contact for more than a few hours in a confined space, without the benefit of all appropriate exposure control measures, with a patient who has a positive AFB smear result or positive culture result for *M. tuberculosis* or is strongly suspicious for being contagious, and who has not met all three criteria (listed on page 8) to indicate that the patient is noncontagious.

*Suspected or confirmed infectious TB cases that trigger contact investigations must be reported promptly to the local Public Health Department.*

Factors that affect the significance of contact include:

- Duration of contact (at least a few hours)
- Proximity of contact
- Use of control measures that are functioning appropriately at the time of exposure (e.g., employee wore a properly fitted N-95 respirator, TB patient was masked, and/or sputum induction was conducted in a well-functioning LEV device)

### **Contact Investigation**

Specify the name or position of the individual responsible for conducting a contact investigation. This person is responsible for the contact investigation, potentially in collaboration with the local Health Department, following any known occupational TB exposure. The contact investigation will begin when employee exposure to a suspected infectious TB case has been identified and results of sputum culture or NAAT for *M. tuberculosis* are pending. The contact investigation will include interviews with the work area supervisor and the patient with suspected infectious TB (index case), if possible. A thorough review of the patient's chart will determine if the patient was transported to the clinic, had laboratory work done, visited radiology, or was interviewed by screening or counseling personnel. A brief memo identifying the patient by initials and date and time of visit will be posted in employee-only areas of all departments where an exposure could have occurred in order to alert those who wish to self-identify. If the index case is an employee, the memo will identify work areas and meetings that may have provided opportunities for exposure without revealing the employee's initials or identity. Suspected or confirmed infectious TB cases that trigger contact investigations must be reported promptly to the local Public Health Department.

### **Screening Following Exposure**

Specify the name or position of the individual responsible for screening employees following occupational exposure to TB. This person is responsible for tuberculin skin testing or providing IGRA and TB symptom screening of employees following occupational TB exposure. A post-exposure baseline TST (for employees with negative TST results) and TB symptom screen will be administered to exposed personnel within 1 week of suspected TB exposure (i.e., positive AFB sputum smear report and clinical findings consistent with pulmonary TB or positive NAAT for *M. tuberculosis*). Employees who have had a negative TST result within the last 3 months may use that test and a new TB symptom screen form as a baseline. Baseline status of employees with past positive TST results will be established by completion of a TB symptom screening form.

If the post-exposure baseline TST result is negative, a second test will be performed 8-10 weeks after the date of the last known exposure.

### **Follow-up and Tracking**

Specify the position title or name of the person who will be immediately notified of all new TST conversions and will track required follow-up care (i.e., chest x-ray, initial follow-up medical evaluation, confirmation of report to local Public Health Department).

## Employee with TB Disease

If the symptom screen, history, physical examination, or chest x-ray are indicative of TB disease, the employee will be excluded from the workplace until:

- TB disease is ruled out based on physical exam, chest x-ray, and bacteriology; or
- TB disease is diagnosed, treated, and the individual is determined to have non-infectious TB as defined under “Symptomatic Employees” on page 59

## Employee TB Exposure Follow-Up

Use this worksheet to track the person or job position responsible for intervention.

POSITION / POSITION RESPONSIBLE	INTERVENTION
	Identifies employees occupationally exposed to TB by interviewing patient, area supervisor, and reviewing patient's chart.
	Writes notification letter and ensures all identified employees are aware of exposure. Places notice on employee bulletin board in all departments in which exposure may have occurred so that employees can self-identify.
	Interviews identified employees to confirm exposure.
	Organizes and tracks screening and TST or IGRA results.
	Places, reads, and interprets TST or IGRA results. Completes TST or IGRA form.
	Evaluates TB symptom screening forms.
	Ensures employee with TST or IGRA conversion or TB symptoms is referred for further evaluation.
	Performs medical history, physical exam, medical management and follow-up, and other related tests, if indicated.
	Records occupational TB infections/TST or IGRA conversions and TB disease on OSHA 300 Log and completes required paperwork.
	Ensures that employees with suspected or known infectious TB do not return to the workplace until their TB is non-infectious.
	Notifies Public Health Department of suspected and confirmed TB cases as required.
	Notifies Public Health Department of TST or IGRA conversions if required.

# Environmental Controls in the Clinic Setting

Environmental controls, the second level of the TB control hierarchy, can reduce the risk of TB infection by decreasing the concentration of *M. tuberculosis* droplet nuclei and exhausting them from a space. For more information about environmental controls, see “Environmental Controls” on page 15.

## Facility Ventilation System Description

Describe the facility’s ventilation system. Examples of ventilation system descriptions include:

- This clinic uses a single-pass air system (air is not recirculated, 100% of supply air comes directly from outdoors, and all air from these areas is exhausted) in the following areas where infectious TB patients receive care:  
\_\_\_\_\_.
- This clinic uses 25% efficient filters in the ventilation system.
- The fan setting on thermostats is maintained in the “on” position whenever the clinic is occupied for continuous air movement and filtration.
- Portable HEPA filter units are used in the following rooms/areas:  
**Note rooms here:** \_\_\_\_\_.
- Permanently-mounted HEPA filter units are located in the following rooms/areas:  
**Note rooms here:** \_\_\_\_\_.
- AIIR(s) are available for isolating persons with suspected or known infectious TB.
- Ultraviolet germicidal irradiation (UVGI) is used in the following areas as an adjunct to ventilation and filtration:  
**Insert areas where UVGI is used here:** \_\_\_\_\_.

Add any additional items that may be in place at your facility.

## Environmental Controls for High-Risk Procedures

High-risk procedures include cough-induction which may and may aerosolize *M. tuberculosis*. Special precautions must be used to prevent occupational exposure when these procedures are performed on a person with suspected or known infectious TB.

Use one of the following statements:

- No high-risk procedures are performed on persons with suspected or known infectious TB at this clinic.
- Special precautions are used to prevent/minimize occupational exposure when high-risk procedures are performed on persons with suspected or known infectious TB.

Use all or part of the following table if high-risk procedures on persons with suspected or known infectious TB are performed at your facility. Do not include the table if high-risk procedures are not performed at your facility.

TABLE 5.

### Ventilation Precautions for High-Risk Procedures

For persons with suspected or known infectious TB

HIGH-RISK PROCEDURES	SPECIAL VENTILATION PRECAUTIONS USED
<ul style="list-style-type: none"> <li>• Sputum induction or sputum collection</li> <li>• Aerosol breathing treatments</li> <li>• Pentamidine treatment (on any patient)</li> </ul>	<p>Local exhaust ventilation booth or tent</p> <p>Local exhaust ventilation hood</p> <p>AllR with 6*-12 air changes per hour (ACH) exhausted directly outdoors away from operable windows, doors, and air intake vents (using HEPA filtration if possible, where human traffic may exist)</p> <p>Performed outdoors only (sputum collection only)</p>
<ul style="list-style-type: none"> <li>• Bronchoscopy</li> <li>• Airway suctioning</li> </ul>	<p>AllR with 6*-12 ACH exhausted directly outdoors away from operable windows, doors, and air intake vents (using HEPA filtration if possible, where human traffic may exist)</p>
<ul style="list-style-type: none"> <li>• Processing specimens for mycobacteriology studies</li> </ul>	<p>Class I or Class II biological safety cabinet (BSC) in a room with All environmental controls</p>

\*6 ACH for existing, pre-1994 facilities

Employees who assist with high-risk procedures in any settings will wear NIOSH-approved N-95 or more protective respirators. Respirators are not required when local exhaust ventilation enclosures are used.

TABLE 6.

## Environmental Controls for Low-Risk Clinics

AREA	RECOMMENDATION	COMMENTS
<b>General Ventilation System</b>	<ul style="list-style-type: none"> <li>Ventilation systems should have minimum 25% efficient filters (MERV 7 or 8)</li> <li>Provide at least 15 CFM of outside air per occupant or 2 air changes per hour (ACH) of outside air, whichever is greater</li> </ul>	25% efficient filters (MERV 7 or 8) remove about 50% of infectious particles in the size range of <i>M. tuberculosis</i> droplet nuclei.
<b>General Waiting Rooms</b>	<ul style="list-style-type: none"> <li>Ten (10) ACH with 2 ACH of outdoor air is recommended for this area</li> <li>Use high efficiency particulate air (HEPA) filter units to increase effective ACH if needed</li> <li>Ultraviolet germicidal irradiation (UVGI) may also be used in this area to supplement ventilation systems</li> <li>Air should flow from clean areas toward less clean areas</li> </ul>	Patients have not yet been screened or diagnosed. Increasing the ACH will dilute infectious particles. Airflow from staff areas (clean areas) toward areas that may be occupied by TB patients (less clean areas) will help to protect clinic staff.
<b>General Exam Rooms</b>	<ul style="list-style-type: none"> <li>Recirculated air should be filtered with minimum 25% efficient filters (MERV 7 or 8)</li> <li>At least 6 ACH are recommended</li> <li>Room should be at neutral or negative pressure relative to adjacent spaces</li> </ul>	
<b>Airborne infection Isolation/Exam Room</b>	<ul style="list-style-type: none"> <li>Probably not needed for low-risk facilities. The occasional person with suspected or known infectious TB can be masked and segregated in a closed room with a small HEPA filter unit, or directed outdoors and referred to a facility with an AIIR</li> </ul>	
<b>Sputum Induction</b>	<ul style="list-style-type: none"> <li>Fully enclosed sputum induction booth with local exhaust ventilation (LEV) is preferred</li> <li>Partially enclosed LEV is the second-best option</li> <li>If LEV is unavailable, any room used for sputum induction should meet all recommendations for an AIIR, including negative pressure, at least 12 ACH, and air exhausted directly outside or HEPA-filtered. Negative pressure should be checked daily when in use</li> </ul>	<p>CDC Guidelines recommend a medium-risk category for facilities performing sputum induction on suspected or confirmed TB patients.</p> <p>Air intake flow should be designed to come in from both sides (in front of patient and health-care worker) and out to the back of patient so that exposure is minimized for the healthcare worker. Negative pressure (direction of flow) should be monitored constantly</p>

TABLE 7.

## Environmental Controls for Medium Risk Clinics and Clinics with Potential Ongoing Transmission

AREA	RECOMMENDATION	COMMENTS
<b>General Ventilation System</b>	<ul style="list-style-type: none"> <li>Ventilation systems should have minimum 25% efficient filters (MERV 7 or 8)</li> <li>Provide at least 15 CFM of outside air per occupant or 2 air changes per hour (ACH) of outside air, whichever is greater</li> </ul>	25% efficient filters (MERV 7 or 8) remove about 50% of infectious particles in the size range of the TB droplet nuclei.
<b>General Waiting Rooms</b>	<ul style="list-style-type: none"> <li>Ten (10) ACH recommended with 2 ACH of outdoor air</li> <li>Use high efficiency particulate air (HEPA) filter units to increase the effective ACH if needed</li> <li>Ultraviolet germicidal irradiation (UVGI) may also be used in this area to supplement ventilation systems</li> <li>Air should flow from clean areas toward less clean areas</li> </ul>	Patients have not yet been diagnosed or screened. Increasing ACH dilutes any infectious particles in the air. Airflow from staff areas (clean areas) toward areas that may be occupied by TB patients (less clean areas) will help to protect clinic staff.
<b>Medium-Risk Waiting Areas</b> such as those in Radiology or Pulmonary Clinics	<ul style="list-style-type: none"> <li>Air from this room should be exhausted or HEPA-filtered before recirculation</li> <li>Ten (10) ACH with 2 ACH of outdoor air is recommended for this area</li> <li>Air should flow from clean toward less clean areas</li> <li>Use portable HEPA filter units to increase effective air change rates if needed</li> <li>UVGI may also be used in this area to supplement ventilation systems</li> </ul>	CDC Guidelines recommend that ambulatory care areas where patients at high risk for TB are treated be ventilated in the same manner as similar in-patient areas.
<b>General Exam Rooms or Interview Rooms</b>	<ul style="list-style-type: none"> <li>Six (6) ACH with 2 ACH of outside air is recommended</li> <li>Room should be at neutral or negative pressure relative to adjacent spaces</li> <li>Use portable HEPA filter units to increase the effective ACH if needed</li> </ul>	
<b>Airborne infection Isolation/Exam Room</b>	<ul style="list-style-type: none"> <li>Recommended for medium-risk clinics</li> <li>At least 12 ACH with 2 ACH of outdoor air recommended</li> <li>Air should be properly discharged outdoors or HEPA-filtered before recirculation</li> <li>Room should be under negative pressure</li> <li>Negative pressure should be monitored at least monthly, and daily when room is in use</li> </ul>	Twelve (12) ACH is the minimum ventilation rate recommended by the CDC for new or renovated AIIRs. The CDC allows 6 ACH for existing pre-1994 AIIRs, but recommends that this be increased to 12 ACH "where feasible." In CNTC experience, 12 ACH is usually feasible. It should be noted that 6 ACH may not satisfy local requirements.
<b>Sputum Induction</b>	<ul style="list-style-type: none"> <li>Fully enclosed sputum induction booth with LEV is preferred. Partially enclosed LEV is the second-best option</li> <li>If LEV is unavailable, any room used as a sputum induction room should meet the requirements for AIIRs, including negative pressure, at least 12 ACH, and air exhausted directly outside or HEPA-filtered. Negative pressure should be checked daily when in use</li> </ul>	CDC Guidelines recommend a medium-risk category for facilities performing sputum induction on suspected or confirmed infectious TB patients. CDC Guidelines recommend that LEV devices are located in an AIIR.

## Maintenance, Monitoring, and Communication

Specify the individual or department responsible for the maintenance, monitoring, and communication of the environmental controls. The following list shows examples of the type of controls to track:

.....  
Mechanical equipment is inspected by \_\_\_\_\_  
and maintained at least yearly, and as needed.  
.....

Filters are inspected quarterly and changed if necessary  
by \_\_\_\_\_.  
.....

Supply and return air registers are cleaned every 6 months and as needed  
by \_\_\_\_\_.  
.....

The negative pressure of airborne infection isolation rooms (AIIRs) and sputum induction  
rooms is checked daily (when in use) by \_\_\_\_\_.  
.....

UVGI bulbs are dusted monthly and changed according to manufacturer's recommen-  
dations by \_\_\_\_\_.  
.....

UVGI warning signage stating, "Caution, High Intensity Ultraviolet Energy, Protect Eyes  
and Skin" is posted by \_\_\_\_\_.  
.....

Engineering and infection control personnel work as a team in efforts to control TB.  
Maintenance and monitoring results are promptly communicated to clinic management/  
infection control staff by \_\_\_\_\_.  
.....

Results of air balance reports and negative pressure checks in AIIRs are copied to clinic  
management/infection control staff by \_\_\_\_\_.  
.....

Shutdowns for maintenance of the ventilation system are coordinated with clinic  
management/infection control staff by \_\_\_\_\_.  
.....

Records of maintenance and monitoring are maintained for 5 years  
by \_\_\_\_\_  
and are located \_\_\_\_\_.  
.....

# Respiratory Protection

The third level of the TB control hierarchy is the use of personal respiratory protection equipment. Respirators are used by HCWs in certain situations in which the risk for exposure to *M. tuberculosis* may not be controlled by administrative or environmental measures alone.

If your clinic is a **low-risk facility**, include the following paragraph in the TB ICP:

This clinic has been designated as a low-risk ambulatory care setting. We have opted to utilize administrative and environmental controls to prevent high-risk exposure situations that require the use of respirators. For example, until they can be transferred to a facility for appropriate evaluation and care, persons with suspected or known infectious TB will be given surgical masks, educated on the importance of keeping the mask in place and changing it when damp, and observed for compliance with this request. This risk designation will be reassessed annually and after any occupational TB exposure.

If your clinic is a **medium-risk facility** include the following paragraphs:

This clinic has been designated as a medium-risk ambulatory care setting. Employees provide care to TB patients and may perform high-risk procedures such as sputum induction. OSHA mandates respirator use for facilities unable to prevent certain high-risk situations via administrative or environmental controls. A respiratory protection program utilizing N-95 respirators has been developed and instituted to enhance staff safety.

Clinic employees are required to wear NIOSH-certified N-95 respirators, which have been approved for protection against TB, when:

- In the presence of a suspected or confirmed infectious TB patient who is unable or unwilling to wear a mask
- Entering a room, including an AIIR, which has been occupied by an unmasked person with suspected or confirmed infectious TB, prior to the time required for 99% of the airborne contaminants to be removed from the room
- Transporting or accompanying a person with suspected or known infectious TB in an enclosed vehicle, even if that patient is wearing a surgical mask
- In the presence of high-risk procedures (e.g., sputum induction)

**[All of the following are OSHA-mandated and should remain in your TB ICP]**

We have selected the following [Insert brand(s) of respirators used here. A selection of sizes must be offered] N-95 respirators for use in this clinic: \_\_\_\_\_.

*Any cluster of employee TST or IGRA conversions will prompt an immediate review and assessment of the TB infection control program.*

## Respiratory Protection Program

If your facility uses respirators, you must have a Respiratory Protection Program that includes a written Respiratory Protection Plan (RPP).

Specify where the written RPP is located. The RPP should include instructions related to:

- Selecting and issuing respirators
- Respiratory protection for bearded employees or individuals unable to use a respirator
- Employee training (including which employees are required to use respirators)
- Conducting respirator fit tests
- Conducting respirator fit checks
- Inspecting respirators
- Cleaning, sanitizing, and maintaining respirators
- Storing and disposing of respirators
- Respirator limitations
- Medical surveillance

**Note:** Additional information and assistance with writing an RPP can be found on the following Web sites:

[http://www.dir.ca.gov/dosh/dosh\\_publications/respiratory.pdf](http://www.dir.ca.gov/dosh/dosh_publications/respiratory.pdf)

<http://www.osha.gov/SLTC/etools/respiratory/oshfiles/writtenprogram1.html>

## TB Infection Control Plan (ICP) Evaluation

The TB ICP should be reviewed at least annually. Specify the name of the individual or committee who will perform the review. The review will include a reassessment of the clinic's risk level (please consult Appendix B [revised version], of the CDC guidelines), including an analysis of any employee TB exposures, employee TST or IGRA conversions, or evidence of person-to-person transmission. Factors that may have contributed to TB exposures or transmission will be reviewed. Interventions to prevent recurrence will be implemented. The TB ICP will be amended to reflect these policy and/or procedure changes.

Any cluster of employee TST or IGRA conversions will prompt an immediate review and assessment of the TB infection control program.