

CDC IMMIGRATION REQUIREMENTS:

Technical Instructions for Tuberculosis Screening and Treatment

Using Cultures and Directly Observed Therapy

October 1, 2009



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Preface

The medical screening for tuberculosis among persons overseas applying for U.S. immigration status and nonimmigrants who are required to have an overseas medical examination, hereafter referred to as applicants, is an essential component of the medical evaluation. Because tuberculosis is a challenging disease to diagnose, treat, and control, these instructions are designed to detect and treat tuberculosis disease among applicants and to reduce the risk of spread of tuberculosis among the U.S. population after immigration.

The instructions in this document supersede all previous Technical Instructions, Updates to the Technical Instructions, memoranda and letters to panel physicians, and memoranda and letters to international refugee resettlement organizations. These instructions are to be followed for tuberculosis screening and treatment among all applicants.

For any questions about these Technical Instructions, please contact the Immigrant, Refugee, and Migrant Health Branch of the Division of Global Migration and Quarantine (DGMQ), Centers for Disease Control and Prevention (CDC), at cdcQAP@cdc.gov or 404-498-1600. These Technical Instructions and other information pertinent to them and the medical examination for applicants for U.S. immigration can be found online at http://www.cdc.gov/ncidod/dq/panel_2007.htm.

Tuberculosis Screening

Any applicant for whom the clinical suspicion of tuberculosis is high enough to warrant treatment for tuberculosis disease, regardless of laboratory results, is considered to have tuberculosis disease and is Class A for Tuberculosis.

Applicants 2-14 years of age living in countries with a World Health Organization (WHO)-estimated tuberculosis incidence rate of ≥ 20 cases per 100,000 population should have a tuberculin skin test or an interferon gamma release assay.

Prior receipt of Bacille Calmette-Guérin (BCG) vaccination does not change the screening requirements or the required actions based on tuberculin skin test results.

A complete screening medical examination for tuberculosis consists of a medical history, physical examination, chest radiography (CXR, when required), determination of immune response to *Mycobacterium tuberculosis* antigens (i.e., tuberculin skin testing [TST] or interferon gamma release assay [IGRA], when required), and sputum testing for *M. tuberculosis* (when required, Figures 1 and 2).

Applicants ≥ 15 years of age require a medical history, physical examination, and CXR. If an applicant has a CXR with findings suggestive of tuberculosis (page 5), has signs and symptoms of tuberculosis (page 5), or has human immunodeficiency virus (HIV) infection, the applicant should provide three sputum specimens to undergo microscopy for acid fast bacilli (AFB), as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level.

Applicants 2-14 years of age living in countries with a World Health Organization (WHO)-estimated tuberculosis incidence rate of ≥ 20 cases per 100,000 population should have a TST or an IGRA. If the TST is ≥ 10 mm or the IGRA is positive or if the applicant has signs and symptoms of tuberculosis or has HIV, a CXR (anteroposterior or posteroanterior view and a lateral view for applicants < 10 years of age; posteroanterior view for applicants ≥ 10 years of age) should be performed. Applicants who have a CXR with findings suggestive of tuberculosis, signs and symptoms of tuberculosis, or HIV infection should provide three sputum specimens to undergo microscopy for AFB, as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level.

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All applicants <2 years of age living in countries with a WHO-estimated tuberculosis incidence rate of ≥ 20 cases per 100,000 population must have a physical examination and history provided by a parent or responsible adult who knows the child best. Those applicants who have signs or symptoms suggestive of tuberculosis or have HIV should have a TST or an IGRA, a CXR (anteroposterior or posteroanterior view and a lateral view), and provide three sputum specimens to undergo microscopy for AFB, as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level. Information about sputum collection in young children can be found in the Laboratory Testing section (Page 6) and in Appendix C.

All applicants <15 years of age living in countries with a WHO-estimated tuberculosis incidence rate of <20 cases per 100,000 population must have a physical examination and history provided by a parent or responsible adult who knows the child best. Those applicants who have signs or symptoms suggestive of tuberculosis or have HIV should have a TST or an IGRA, a CXR (anteroposterior or posteroanterior view and a lateral view for applicants <10 years of age; posteroanterior view for applicants ≥ 10 years of age) and provide three sputum specimens to undergo microscopy for AFB, as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level.

Pulmonary tuberculosis is a disease that involves the lung parenchyma and is often infectious (i.e., contagious [determined by sputum smear examination for AFB and mycobacterial culture]). Laryngeal tuberculosis is rare but highly infectious. Disease of the lung parenchyma may occur concurrently with pleural tuberculosis, and the parenchymal lung disease may not be apparent on chest radiograph due to compression of affected lung tissue by pleural fluid. Because the emphasis for pre-immigration medical evaluation is on infectiousness, for the purpose of this document the term pulmonary tuberculosis refers to disease of the lung parenchyma, pleural tuberculosis, and laryngeal tuberculosis.

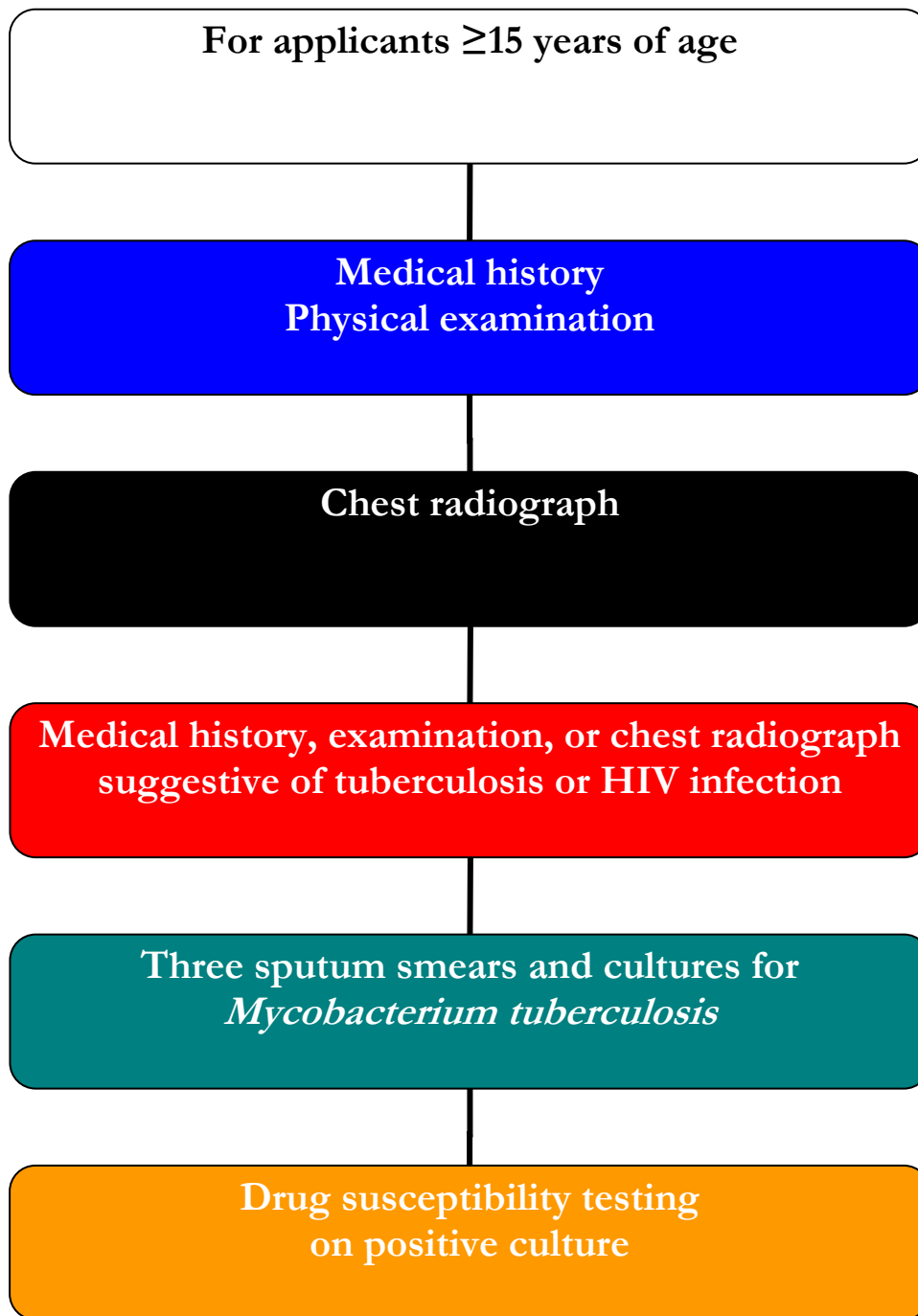


Figure 1: Tuberculosis screening medical examination for applicants ≥ 15 years of age in countries with a WHO-estimated tuberculosis incidence rate < 20 cases per 100,000 population.

Technical Instructions for Panel Physicians

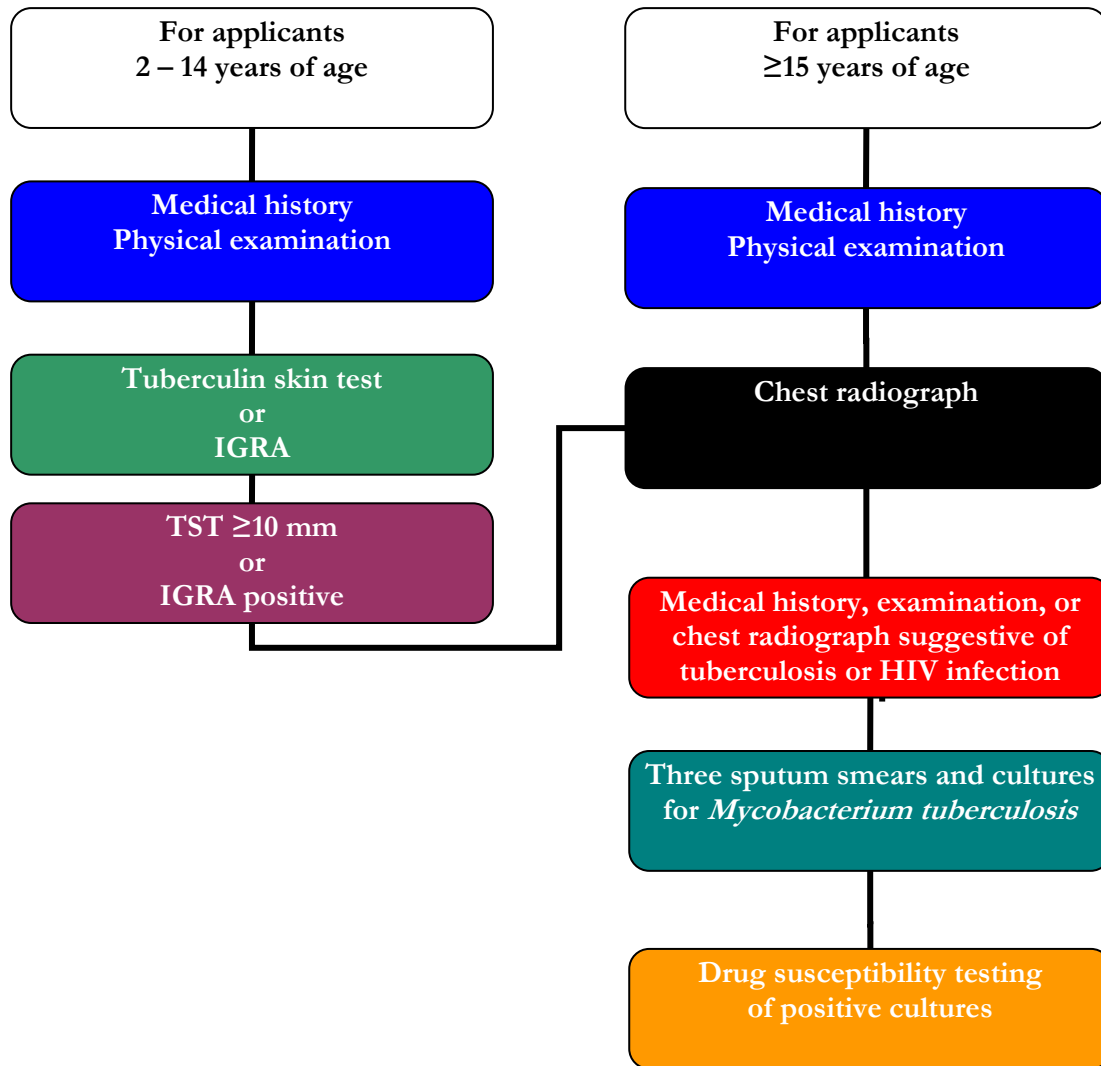


Figure 2: Tuberculosis screening medical examination for applicants ≥ 2 years of age in countries with a WHO-estimated tuberculosis incidence rate ≥ 20 cases per 100,000 population.

Each aspect of the examination is detailed below:

Medical History

- The medical history should focus on risk factors for tuberculosis disease, including previous history of tuberculosis; illness suggestive of tuberculosis (such as cough of >3 weeks' duration, dyspnea, weight loss, fever, or hemoptysis); prior treatment suggestive of tuberculosis treatment; and prior diagnostic evaluation suggestive of tuberculosis. The clinical expression of tuberculosis may be different in children than adults, and for children may only include generalized findings such as fever, night sweats, growth delay, and weight loss. Children are also more prone to extrapulmonary tuberculosis, such as meningitis, and disease of the middle ear and mastoid, lymph nodes, bones, joints, and skin.
- The medical history should also include inquiries regarding family or household contact with a person who has or had tuberculosis or illness, treatment, or diagnostic evaluation suggestive of tuberculosis.
- Prior receipt of Bacille Calmette-Guérin (BCG) vaccination should be ascertained; review and record if documentation and date of receipt are available.

Physical Exam

- Pertinent elements of the physical exam for tuberculosis include general characteristics such as height, weight, temperature, heart rate, respiratory rate, and blood pressure; a thorough pulmonary examination; inspection and palpation of appropriate lymph nodes; and inspection for scars of scrofula and prior chest surgery.

Chest Radiography

When performed, chest radiography (CXR) should consist of a standard posteroanterior view for all applicants ≥ 10 years of age. Applicants < 10 years of age who receive a CXR should have a standard anteroposterior or standard posteroanterior view and should also have a lateral view. If a child receives a posteroanterior view, the CXR should be labeled "PA" for the benefit of radiologist's review.

Chest radiographs should be interpreted by a radiologist and reviewed by the panel physician. Documentation of the results for the chest radiographs should be available within 1 week from the time the CXR was performed. CXRs of any applicants, especially children, should be re-taken if the initial CXR is suboptimal due to factors such as incorrect penetration or motion artifact. CXR interpretations should include comparisons with prior CXRs, if available.

Women who are pregnant are required to have a CXR to immigrate. Pregnant women must provide consent for the CXR. Pregnant women receiving chest radiographs should be provided abdominal and pelvic protection with double-layer, wrap-around lead shields.

Immune Response to *M. tuberculosis* Antigens

- Applicants 2-14 years of age living in countries with a WHO-estimated tuberculosis incidence rate of ≥ 20 cases per 100,000 population should have determination of immune response to *M. tuberculosis* antigens through placement of a TST or performance of an IGRA. Exceptions include applicants with written documentation from a physician of a previous TST reaction ≥ 10 mm or a positive IGRA. For TST, the written documentation must include date of the test, millimeters of induration, type of PPD used, and the testing physician's name and office information. For IGRA, the written documentation must include date of the test, type of IGRA performed, test results in standard units of measurement, the test interpretation (e.g., positive, negative, indeterminate, borderline), and the testing physician's name, signature and office information. Applicants 2-14 years of age with a documented previous history of tuberculosis disease should have a CXR, even if their TST < 10 mm or IGRA is negative.

Panel physicians should be advised that some experts prefer TST in children younger than 5 years of age. There are relatively few published reports documenting the performance of IGRAs in young children, obtaining sufficient blood is more difficult, and there is concern that IGRAs may perform differently in very young children who are at greater risk of a poor outcome if infection is undiagnosed.

- TST

Purified protein derivative (PPD) should be administered intradermally by the Mantoux method. Ideally, preparations used should be equivalent to 5TU PPD-S. However, in countries where such preparations are limited or impossible to import, panel physicians should use PPD preparations that are approved for use by their Ministries of Health. The type of PPD used should be documented.

- IGRA

Interferon gamma release assays are blood tests that measure a component of cell-mediated immune reactivity to *M. tuberculosis* in fresh whole blood. CDC allows the use of QuantiFERON®-TB Gold (QFT-G), QuantiFERON®-TB Gold In Tube (QFT-G IT), or T-SPOT® by panel physicians. Panel physicians should follow the manufacturers' written instructions for performing the examinations and interpreting test results. For the purpose of tuberculosis screening according to these Technical Instructions, an indeterminate test result should be viewed as a negative result. However, applicants with an indeterminate test result should be advised to have a repeat test after arrival to the United States. IGRA test results in their unit of measurement should be documented, even for those with negative or indeterminate results.

Laboratory Testing

- Laboratory examination for tuberculosis disease should consist of at least three sputum specimens, which should undergo microscopy for AFB as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level (Appendix B, Appendix C). Specimens reported as negative should be cultured for a minimum of 6 weeks, with a final report produced within 8 weeks of collection. Positive cultures need to be reported as soon as the results are known.
- Applicants unable to produce sputum specimens, such as young children, are required to have alternative methods of sputum collection performed (e.g., early morning gastric aspirates or sputum induction or both [Appendix C]) to determine their tuberculosis status.
- Positive *M. tuberculosis* cultures shall undergo drug susceptibility testing (DST) for isoniazid, rifampin, ethambutol, pyrazinamide, and streptomycin. Panel physicians must have access to DST results within 10 weeks of sputum collection.
- Positive *M. tuberculosis* cultures that are resistant to isoniazid and rifampin shall undergo drug susceptibility testing on second-line tuberculosis medications. At a minimum, second-line testing should include testing for resistance against ethionamide, a fluoroquinolone (e.g., ofloxacin, levofloxacin, moxifloxacin), amikacin, capreomycin, and para-aminosalicylic acid (PAS).
- The laboratory requirements in these instructions do not preclude panel physicians from using additional tests for tuberculosis that they may have access to, such as the Hain GenoType® MTBDRplus assay. Panel physicians should only use only tests that have garnered regulatory approval in the country in which they would be used and only use the tests only for the purposes for which they have been approved. Panel physicians may base treatment decisions on the results of regulatory-approved tests for tuberculosis.

In addition to the recommendations provided, panel physicians should use their clinical judgment in the evaluation and treatment of the applicant.

Many applicants may have previously received BCG vaccination. Prior receipt of BCG does not change the screening requirements or the required actions based on those results.

Detection of tuberculosis disease necessitates a combined clinical and public health response to cure individual tuberculosis patients, stop transmission, and enable safe movement to the United States.

For additional guidance for resettlement of large refugee groups, see Appendix E.

Tuberculosis Screening Results and Travel Clearance

The evaluation is complete when all required aspects of the medical examination have been completed, including a final report of culture results, and the applicant can be assigned a Tuberculosis Classification.

Travel clearances are valid for 6 months from the time the evaluation is complete for applicants who have no Tuberculosis Classification or only Class B2 TB or Class B3 TB and who do not have HIV infection.

Travel clearances are valid for 3 months from the time the evaluation is complete for applicants who are Class B1 TB, Pulmonary or Class B1 TB, Extrapulmonary or who have HIV infection.

Applicants who do not travel within the clearance period will need to restart the tuberculosis screening process.

Any applicant diagnosed with pulmonary or laryngeal tuberculosis who needs treatment is not cleared for travel until completion of successful treatment, regardless of the diagnostic criteria.

It is important that tuberculosis disease be correctly diagnosed among applicants for U.S. immigration. Correct diagnosis of tuberculosis will ensure that applicants with tuberculosis disease receive correct treatment, reduce further spread of the disease, and reduce the likelihood of treating applicants who do not have the disease, thus unnecessarily delaying their immigration.

Applicants with clinical and radiographic findings suggestive of common bacterial infections of the upper and lower respiratory tract may be treated with a course of antibiotics. However, fluoroquinolones should not be used for empiric treatment of respiratory infections because they are a mainstay of second-line tuberculosis therapy and their use could both result in mistreatment of tuberculosis and lead to drug-resistant tuberculosis. After treatment for lower respiratory infections, the CXR for medical screening should not be performed until at least 8 weeks after therapy, unless the applicant's clinical status warrants further evaluation earlier than 8 weeks after therapy. *Table 1: Tuberculosis screening results, travel clearance, and actions* lists screening results and required actions for those results.

Table 1: Tuberculosis screening results, travel clearance, and actions.

Medical History	Physical Exam	Chest Radiograph	TST or IGRA*	Sputum Smears	Culture for Mycobacterium	Travel Clearance	Action or TB Classification†
Normal	Normal	Normal	Negative	NA	NA	6 months‡	No TB Classification
Normal	Normal	Normal	Positive	NA	NA	6 months‡	Class B2 TB, LTBI Evaluation
Normal	Normal	Normal	Negative	Negative	Negative	3 months§	No TB Classification
Normal	Normal	Normal	Positive	Negative	Negative	3 months§	Class B2 TB, LTBI Evaluation¶
Normal	Normal	Normal	Negative or Positive	Either positive		No	Class A, Treatment
Any component suggestive of TB			Negative or Positive	Negative	Negative	No	Use clinical judgment¶
Any component suggestive of TB			Negative or Positive	Either positive		No	Class A Treatment
Any component suggestive of TB			Negative or Positive	Negative	Negative	No	Use clinical judgment¶
Any component suggestive of TB			Negative or Positive	Either positive		No	Class A, Treatment
Completed therapy for tuberculosis			Negative or Positive	Negative or Positive	Negative	3 months§	Class B1 TB, Pulmonary
Completed therapy for tuberculosis			Negative or Positive	Negative or Positive	Negative	3 months§	Class B1 TB, Pulmonary

* When required. TST and IGRA results have no bearing on travel clearance.

† All contacts must receive a Class B3 TB, Contact Evaluation classification unless they are Class A or have extrapulmonary disease.

‡ From the time the evaluation is complete.

§ Travel clearance is for 3 months from the time the evaluation is complete; culture results must be known within 8 weeks of collection.

¶ Tuberculosis treatment should not be initiated for applicants who are smear- and culture-negative unless the CXR and clinical findings are highly suggestive of tuberculosis disease. If cleared to travel, their tuberculosis classification will be Class B1 TB, Pulmonary.

Screening Results and Travel Clearance

- Applicants without clinical findings of tuberculosis, without HIV infection, and with a normal CXR (and for children 2-14 years of age, a TST <10 mm or negative IGRA) can be cleared for travel to the United States (Table 1). Applicants should be assigned a tuberculosis classification (No TB Classification).
- Applicants 2-14 years of age who have a TST ≥ 10 mm or a positive IGRA and are without HIV infection, have no clinical findings of tuberculosis, and have a normal CXR can be cleared for travel to the United States. Such applicants should be assigned a tuberculosis classification to receive evaluation for LTBI in the United States (Class B2 TB, LTBI Evaluation).
- Applicants with signs or symptoms suggestive of tuberculosis, a CXR suggestive of tuberculosis disease, or HIV infection shall have three sputum specimens to undergo microscopy for acid-fast bacilli (AFB), as well as culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level. Any laboratory or additional studies shall be performed that are deemed necessary, either as a result of the physical examination or pertinent information elicited from the applicant's medical history for the panel physician to reach a conclusion about the presence or absence of tuberculosis (TB classification pending).
- Applicants with HIV infection should have three sputum specimens sent to the laboratory for AFB microscopy and culture. These applicants cannot be cleared for travel until the results of the laboratory investigation are available (TB classification pending).
- Applicants who have sputum smears that are positive for AFB microscopy should not be cleared for travel and should be started on treatment for tuberculosis disease (Class A TB). If the culture results are negative or demonstrate nontuberculous mycobacteria (NTM), panel physicians should use their clinical judgment in determining whether to continue treatment for tuberculosis disease. If applicants have NTM and the panel physician does not feel further treatment for tuberculosis disease is warranted, those applicant may be cleared for travel. The presence of NTM should be documented on the DS Forms. Applicants who had an abnormal CXR or signs and symptoms suggestive of tuberculosis disease should be assigned a Class B1 TB, Pulmonary classification.
- Applicants who have negative sputum smears and positive *M. tuberculosis* cultures should not be cleared for travel and should be treated for tuberculosis (Class A TB).

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- Applicants diagnosed with extrapulmonary tuberculosis only (except for laryngeal or pleural tuberculosis) can be cleared for travel. Applicants should be assigned a tuberculosis classification (Class B1 TB, Extrapulmonary). Efforts should be made to obtain a laboratory-confirmed diagnosis. Applicants with extrapulmonary tuberculosis should be considered for treatment if departure is not planned within 3 months or if withholding therapy would be harmful. Applicants with extrapulmonary disease who are started on therapy prior to departure should be instructed of the importance of completing therapy after their arrival in the United States. They should be given a 14-day supply of medication at departure. Because patients with laryngeal and pleural tuberculosis can be infectious, they must complete therapy before departure.
- A diagnosis of extrapulmonary tuberculosis does not preclude an evaluation for pulmonary tuberculosis within the specified time frames. Applicants with extrapulmonary tuberculosis (except for laryngeal and pleural tuberculosis) do not have to provide sputum smears unless they have signs or symptoms suggestive of tuberculosis disease, an abnormal CXR suggestive of tuberculosis, or have HIV infection.
- Applicants who have negative sputum smears and cultures, but have one of the cultures reported as “contaminated,” may still be cleared for travel. When applicants have >1 contaminated cultures, panel sites and their designated laboratories should review their procedures and collect three additional sputum specimens from the applicant for AFB microscopy and culture.
- Applicants diagnosed with tuberculosis disease by panel physicians and who are not treated at treatment centers approved by DGMQ should not be cleared for travel. These applicants will need to repeat their medical screening examination 1 year after treatment was completed. If the tuberculosis examination is negative at that time, the applicant can be cleared for travel. The applicant should receive a Class B1 TB, Pulmonary classification, and their treatment location, including physician name and clinic city and state, should be documented on the DS Forms. A written treatment summary must be presented by the applicant from the treating provider and attached to the travel documents of the applicant.
- Applicants 10 years of age or younger who require sputum cultures, regardless of HIV infection status, may travel to the United States immediately after sputum smear analysis (while culture results are pending) if none of the following conditions exist:
 - Sputum smears are positive for acid-fast bacilli (AFB). If the applicant could not provide sputum specimens and gastric aspirates were obtained, positive gastric aspirates for AFB do not prevent travel while culture results are pending.
 - Chest radiograph findings include—
 - One or more cavities
 - Extensive disease (e.g., particularly if involving both upper lobes)
 - Respiratory symptoms include forceful and productive cough
 - Known contact with a person with multidrug-resistant tuberculosis (MDR TB) who was infectious at the time of contact

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For applicants 10 years of age or younger who travel to the United States while results of cultures are pending, panel physicians should—

- Give the applicant a Class B1 TB, Pulmonary classification
- Document that culture results are pending on the Chest X-Ray Worksheet (DS 3030)
- Forward culture results to DGMQ “Quality Assessment Program” via fax at 404-639-4441 so that DGMQ can forward the culture results to the receiving health departments

For applicants 10 years of age and younger, panel physicians should provide the DS Forms based on the date of intended travel. If an applicant 10 years of age or younger will not travel until after culture results are to be reported (assuming they are negative), the panel physicians should wait until that time before completing the DS Forms. If the applicant 10 years of age or younger will travel while results of cultures are pending, the panel physician should provide DS Forms while cultures are pending.

Tuberculosis Treatment

All applicants with pulmonary or laryngeal tuberculosis disease who need treatment overseas will need to complete directly observed therapy (DOT) prior to U.S. immigration.

Applicants diagnosed with possible tuberculosis disease who are smear and culture negative should not have treatment begun overseas unless the CXR and clinical findings are highly suggestive of tuberculosis disease.

**Follow current ATS/CDC/IDSA guidelines
(http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/Treatment.htm).**

Use only quality-assured drugs. Consult the World Health Organization (WHO) Global Drug Facility (GDF) for first-line drugs and the International Dispensary Association (IDA, Amsterdam) or WHO Green Light Committee for second-line drugs.

For panel physicians not wanting to treat tuberculosis patients themselves, the Division of Global Migration and Quarantine will identify national or other in-country programs that follow these standards. Treatment will need to be supervised by panel physicians using these standards or by programs identified by the Division of Global Migration and Quarantine.

Treatment of tuberculosis, both pulmonary and extrapulmonary, should be administered following DOT policies and practices during the entire course of therapy. DOT is an adherence-enhancing strategy in which a health-care worker or other trained person watches a patient swallow each dose of medication. Directly observed therapy is the standard care for all applicants with tuberculosis disease.

Applicants with positive sputum smears or positive cultures who do not want to be treated may not travel to the United States. Panel physicians should notify the Consulate of any Class A applicants refusing tuberculosis treatment at a designated DOT facility. The panel physician has an ethical obligation to make good-faith efforts to treat patients, including notifying public health officials if efforts to treat them fail. Panel physicians should notify the appropriate public health officials in their jurisdiction when they diagnose an applicant with tuberculosis disease.

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Applicants, including children, who are diagnosed with possible tuberculosis disease but have negative sputum smears and negative cultures, can be given consideration for not initiating therapy prior to departure. Treatment should only be initiated only if the CXR and clinical findings are highly suggestive of tuberculosis disease. Applicants who begin therapy under these circumstances should be re-evaluated clinically and radiographically after 2 months of treatment. Treatment should be continued only if there is evidence of clinical and/or radiographic improvement.

Treatment of U.S. applicants should be administered consistent with the current American Thoracic Society (ATS)/CDC/Infectious Diseases Society of America (IDSA) guidelines for treatment of tuberculosis, including being guided by drug-susceptibility testing results (http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/Treatment.htm). These guidelines are consistent with International Standards for Tuberculosis Care (Tuberculosis Coalition for Technical Assistance, The Hague: 2006). Sites may not substitute local treatment standards for ATS/CDC/IDSA standards for these applicants.

Identification of an applicant with multidrug-resistant tuberculosis (MDR TB) should be reported to DGMQ (cdcQAP@cdc.gov or fax: 404-639-4441) within 1 week of receipt of the DST report.

Treatment of MDR TB should be done by or in close consultation with experts in the management of such cases and in coordination with DGMQ. Panel physicians and DGMQ-identified treatment programs should have direct access to tuberculosis treatment expertise for consultation regarding care of complex tuberculosis cases. DGMQ, in consultation with the Division of Tuberculosis Elimination (DTBE), will identify tuberculosis consultants. Documentation of consultation with a tuberculosis expert should be maintained and forwarded by the panel physician to DGMQ within 1 week of consultation. Additional written guidance on treatment of drug-resistant tuberculosis can be found in “Drug-resistant tuberculosis: a survival guide for clinicians” by the Francis J. Curry National Tuberculosis Center and California Department of Health Services, San Francisco, California (http://www.nationaltbcenter.edu/products/product_details.cfm?productID=WPT-11).

For applicants who present for the medical examination already on tuberculosis treatment begun elsewhere or for applicants diagnosed with tuberculosis who transfer into a DGMQ-designated DOT program, therapy should be continued in the following manner:

- As soon as patients transfer into the DOT program, they should provide three sputum specimens for AFB analysis and culture. Positive isolates should undergo drug susceptibility testing. If drug resistance is detected, the patient’s regimen should be modified accordingly.
- The patients should continue their treatment regimen according to the ATS/CDC/IDSA guidelines and provide sputum monitoring as described in these TB TI.
- If the patient was being treated by using a WHO continuation phase of 6 months of isoniazid and ethambutol (which is not consistent with the ATS/CDC/IDSA guidelines):
 - If the applicant has completed 2 months or less of the 6-month isoniazid and ethambutol continuation phase (and has no drug resistance), the 6-month isoniazid and ethambutol continuation phase should be stopped and the patient should be started on the standard 4-month continuation phase of isoniazid and rifampin.

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- If the patient has completed >2 months of the 6-month isoniazid and ethambutol continuation phase (and has no drug resistance), the patient should complete the 6-month isoniazid and ethambutol continuation phase.
- For the benefit of receiving health departments, for those patients who complete a 6-month isoniazid and ethambutol continuation phase, please document that this is a WHO-approved regimen.

For panel physicians who do not want to perform tuberculosis therapy, DGMQ will identify programs that adhere to these standards. When applicants are sent for treatment to national or other in-country programs that are approved by DGMQ, panel physicians should collaborate with these designated treatment programs to help ensure adequate completion of therapy for the applicants.

Applicants treated at non-DGMQ-designated treatment sites will need to provide documentation of their treatment summary to demonstrate having completed tuberculosis treatment. A letter from a physician stating they were treated is not sufficient. Documentation of treatment should include—

- Medication names
- Dosages of medications
- Dates of delivery of each medication
- Results of sputum smear, culture, and DST results performed by the nondesignated treatment center
- Reports of CXR performed by the nondesignated treatment center

Without this documentation, the applicant may not be further considered for travel to the United States.

Waivers

A provision allows applicants undergoing pulmonary or laryngeal tuberculosis treatment to petition for a Class A waiver.

Waivers should be pursued for any immigrant or refugee who has a complicated clinical course and would benefit from receiving tuberculosis treatment in the United States.

Applicants diagnosed with tuberculosis disease who are both smear- and culture-negative and will be traveling to the United States prior to start of treatment do not need to complete the waiver process.

In exceptional medical situations, a provision allows applicants undergoing pulmonary tuberculosis treatment to petition for a Class A waiver. Form I-601 or I-602 (for immigrants or refugees, respectively) must be completed. These petitions are reviewed by the Department of Homeland Security on an individual basis and considered in situations with extenuating medical circumstances and also sent to DGMQ to also review. DGMQ reviews the application and provides an opinion regarding the case to the requesting entity (DOS or DHS). DHS then has the final authority to adjudicate the waiver request. Because tuberculosis disease in young children is very challenging, CDC supports the filing of waiver requests for young children with tuberculosis disease so that the waiver request may be reviewed and adjudicated in a timely manner.

All requests for waivers need to be accompanied by prior notification and approval by the U.S.-based physician accepting responsibility for the applicant's continued care and treatment and the U.S. health department with jurisdiction.

Tuberculosis Treatment Monitoring

These guidelines in the Technical Instructions use drug-susceptibility testing results to determine the frequency of laboratory testing during drug treatment.

Children <10 years of age with drug-susceptible or culture-negative tuberculosis who cannot provide sputum specimens will not need to provide induced sputum or gastric aspirate specimens during treatment, unless their clinical course warrants an evaluation.

When signs of clinical worsening occur during therapy, such as persistent weight loss, fever, cough, or worsening CXR, repeat sputum smears, cultures, and DST are indicated.

These guidelines for treatment monitoring differ from recommendations in the ATS/CDC/IDSA guidelines and “Drug-resistant tuberculosis: a survival guide for clinicians” by the Francis J. Curry National Tuberculosis Center and California Department of Health Services.

- **Drug-susceptible:** two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy until cultures are negative for 2 consecutive months. Two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy.
- **Resistant to only one drug (including resistant to only isoniazid or rifampin):** two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy until cultures are negative for 2 consecutive months. Two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy.
- **Resistant to more than one drug but susceptible to isoniazid or rifampin (drug resistant but not MDR TB):** two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy until cultures are negative for 2 consecutive months. Two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy.
- **MDR TB (resistant at least to both isoniazid and rifampin):** two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy. Two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy.
- **No drug susceptibility testing results (culture negative):** one sputum specimen should be collected and submitted for AFB microscopy and mycobacteria culture once a month during therapy. Two sputum specimens should be collected and submitted for AFB microscopy and mycobacteria culture at the end of therapy.

Contacts of Tuberculosis Cases

Contacts of persons with pulmonary tuberculosis disease should be removed from exposure to the person with tuberculosis.

All contacts should receive a TST or IGRA.

Contacts who have clinical findings or CXR findings suggestive of tuberculosis should provide at least three sputum specimens for AFB microscopy and mycobacteria culture.

A contact is a person who has shared the same enclosed air space (i.e., exposed) in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a person with a smear-positive and/or culture-positive pulmonary tuberculosis case. Contacts exposed in this fashion to persons with smear-positive or culture-positive pulmonary tuberculosis are at increased risk of infection with *M. tuberculosis*. The end of contact occurs when the tuberculosis case is isolated from others or the sputum smears become negative.

Panel physicians should notify the appropriate public health authorities in their jurisdiction when they diagnose an applicant with pulmonary tuberculosis. Contacts of cases who are applicants for U.S. immigration should be evaluated for tuberculosis disease by the panel physician. All such contacts should receive a TST or IGRA.

If the TST is ≥ 5 mm or IGRA is positive, the contact should be further evaluated with medical history, physical examination, and CXR. If the contact is not started on LTBI therapy, he or she should receive an evaluation with medical history, physical examination, and CXR every 3 months until departure.

If the TST is < 5 mm, IGRA is negative, and the contact is not placed on prophylaxis, the TST or IGRA should be repeated every 3 months until ≥ 8 weeks after contact ends, the index case has negative sputum smears for 2 consecutive months, or TST becomes ≥ 5 mm or IGRA becomes positive.

Contacts with clinical findings or CXR suggestive of tuberculosis disease should provide three sputum specimens to undergo microscopy for AFB and culture for mycobacterium. Contacts diagnosed with tuberculosis disease will need to complete tuberculosis treatment prior to U.S. immigration.

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Contacts who have a negative evaluation for tuberculosis disease may be cleared for travel. These applicants should be assigned a tuberculosis classification (Class B3 TB, Contact Evaluation).

All contacts who travel <8 weeks after contact ends should receive a Class B3 TB, Contact Evaluation classification, and their TST or IGRA results should be documented.

Contacts who travel ≥ 8 weeks after contact ends and have a TST or IGRA done ≥ 8 weeks after the end of contact that is <5 mm (TST) or negative (IGRA) should not receive a Class B3 TB, Contact Evaluation classification. If the TST is ≥ 5 mm or IGRA is positive, they should receive a Class B3 TB, Contact Evaluation classification and a Class B2 TB, LTBI Evaluation classification.

Contacts who had clinical findings or CXR suggestive of tuberculosis and had a negative sputum analysis for AFB and mycobacteria culture should be classified as Class B1 TB, Pulmonary, as specified earlier in these Technical Instructions. They would also receive a Class B3 TB, Contact Evaluation classification.

In general, preventive therapy (i.e., treatment of LTBI) should not be initiated overseas. Exceptional situations in which preventive therapy should be initiated overseas include certain pediatric contacts (see next paragraph) and contacts with impaired immunity (e.g., HIV infection).

- Children <4 years of age and applicants with impaired immunity (e.g., HIV infection) who are contacts of a known pulmonary tuberculosis case, regardless of how that case was diagnosed, and who have a negative evaluation for tuberculosis disease, should begin directly observed preventive therapy (DOPT) regardless of TST or IGRA results. Isoniazid may be used except in known exposures to a tuberculosis case with MDR TB or isoniazid resistance. Advice on other preventive regimens should be sought from experts identified by DGMQ. Children and applicants with impaired immunity (e.g., HIV infection) receiving preventive therapy should have a TST or IGRA 8 weeks after conclusion of exposure to the infectious case. Preventive therapy may be discontinued if the TST is <5 mm or IGRA is negative 8 weeks after conclusion of exposure to the infectious case. Children and applicants may be cleared for travel while on preventive therapy and should be assigned a tuberculosis classification (Class B3 TB, Contact Evaluation) to ensure follow-up in the United States.

If an applicant does not complete preventive tuberculosis treatment prior to departure, a 30-day supply of medication and instructions on how to take it should be given to the applicant or the parent or responsible adult traveling with the applicant. All pertinent documentation should indicate the applicant's status so that the applicant can receive expedited follow-up upon arrival to the United States.

Panel physicians do not need to wait to classify an applicant who are a contact to someone suspected of having tuberculosis disease until the person they are a contact to has culture results returned. If someone leaves for the United States and you later learn that a contact of theirs has a

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positive culture, please forward to the DGMQ office (via fax at 404-639-4441) that information and DGMQ can forward the contact information to the receiving health department.

Tuberculosis Classifications and Descriptions

Applicants should be assigned one or more tuberculosis classifications on the DS Forms.

The tuberculosis classifications and descriptions are listed below. Applicants may have more than one TB Classification. However, they cannot be classified as both Class B1 TB and Class B2 TB. In addition, applicants cannot be classified as Class B3 TB, Contact Evaluation if they are Class A or Class B1 TB, Extrapulmonary.

No TB Classification

Applicants with normal tuberculosis screening examinations.

Class A TB with waiver

All applicants who have tuberculosis disease and have been granted a waiver.

Class B1 TB, Pulmonary

No treatment

- Applicants who have medical history, physical exam, or CXR findings suggestive of pulmonary tuberculosis but have negative AFB sputum smears and cultures and are not diagnosed with tuberculosis or can wait to have tuberculosis treatment started after immigration.

Completed treatment

- Applicants who were diagnosed with pulmonary tuberculosis and successfully completed directly observed therapy prior to immigration. The cover sheet should indicate if the initial sputum smears and cultures were positive and if drug susceptibility testing results are available.

Class B1 TB, Extrapulmonary

Applicants with evidence of extrapulmonary tuberculosis. The anatomic site of infection should be documented.

Class B2 TB, LTBI Evaluation

Applicants who have a tuberculin skin test ≥ 10 mm or positive IGRA but otherwise have a negative evaluation for tuberculosis. The size of the TST reaction or IGRA result, the applicant's status with respect to LTBI treatment, and the medication(s) used should be documented. For applicants who had more than one TST or IGRA, all dates and results and whether the applicant's TST or IGRA converted should be documented. Contacts with TST ≥ 5 mm or positive IGRA should receive this classification (if they are not already Class B1 TB, Pulmonary).

Class B3 TB, Contact Evaluation

Applicants who are a recent contact of a known tuberculosis case. The size of the applicant's TST reaction or IGRA response should be documented. Information about the source case, name, alien number, relationship to contact, and type of tuberculosis should also be documented.

Documentation

All medical documentation, including original laboratory reports, must be included with the required DS Forms.

All required medical documentation should be sent by courier or other secure means to the U.S. Embassy for all Class A and Class B1 conditions. All Class A and Class B1 tuberculosis conditions should be reported to the U.S. Embassy upon detection.

All data that can be submitted electronically to CDC/DGMQ should be sent at the time of departure.

Department of State forms DS-2054, DS-3025, DS-3026, and DS-3030 must be completed in their entirety and included in the applicant's travel packet. This includes assigning a tuberculosis classification on the DS-2054 and DS-3030. Incomplete documentation may result in refusal to grant a visa or designation of medical hold status at arrival to ports of entry.

For applicants requiring tuberculosis treatment prior to U.S. immigration, the panel physician is required to document the following:

1. **Chest radiograph findings** before, during, and after treatment as recorded on the DS 3030.
2. **Tuberculin skin test** documentation should include date of TST reading, name of product, expiration date, amount administered, and the type of product used (e.g., 5TU PPD-S), and results in millimeters of induration.
3. **Interferon Gamma release assay** results should include type of IGRA used (i.e., Quantiferon® or T-SPOT®), expiration date, and test result including units of measurement.
4. **Sputum smear** AFB microscopy results obtained before, during, and after treatment.
5. **Cultures for mycobacteria** results obtained before, during, and after treatment, including cultures that were contaminated.
6. **Drug susceptibility test results** performed on any positive cultures.
7. **DOT regimen** received (including doses of all medications), start date, and completion date, and any periods of interruption.
8. **Clinical course** such as clinical improvement or lack of improvement during and after treatment, including resolution of symptoms and signs and weight stability or gain.
9. **Pre-departure screening** evaluations, when required by CDC (screening that is performed within 3 weeks of departure).

APPENDIX A GLOSSARY OF ABBREVIATIONS

ATS	American Thoracic Society
BCG	Bacille Calmette-Guérin
CDC	Centers for Disease Control and Prevention, United States
CXR	Chest radiograph
DGMQ	Division of Global Migration and Quarantine
DOPT	Directly observed preventive therapy
DOT	Directly observed therapy
DST	Drug-susceptibility testing
DTBE	Division of Tuberculosis Elimination
FDA	U.S. Food and Drug Administration
GAP	Global AIDS Program
GDF	WHO Global Drug Facility
HEPA	High-efficiency particulate air (filter)
HIV	Human immunodeficiency virus
IDA	International Dispensary Association
IDSA	Infectious Diseases Society of America
IGRA	Interferon gamma release assay
LTBI	Latent tuberculosis infection
MDR TB	Multidrug-resistant tuberculosis
PPD	Purified protein derivative
QFT-G	QuantiFERON®-TB Gold test
TST	Tuberculin skin test
WHO	World Health Organization

APPENDIX B DEFINITIONS

Contact – a person who has shared the same enclosed air space (i.e., exposed) in a household or other enclosed environment for a prolonged period (days or weeks, not minutes or hours) with a person with a smear- and/or culture-positive pulmonary tuberculosis case. Contacts exposed in this fashion to persons with smear- or culture-positive pulmonary tuberculosis are at increased risk of infection with *M. tuberculosis*.

Directly observed therapy (DOT) – adherence-enhancing strategy in which a health-care worker or other trained person watches a patient swallow each dose of medication. Directly observed therapy is the standard care for all applicants with tuberculosis disease.

Drug susceptibility test (DST) – a laboratory determination to assess whether an *M. tuberculosis* complex isolate is susceptible or resistant to antituberculosis drugs that are added to mycobacterial growth medium or are detected genetically. The results predict whether a specific drug is likely to be effective in treating tuberculosis disease caused by that isolate.

Extensively drug-resistant tuberculosis disease (XDR TB) – tuberculosis disease caused by *M. tuberculosis* organisms that are resistant to isoniazid and rifampin, plus resistance to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

Extrapulmonary tuberculosis – tuberculosis disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes). The presence of extrapulmonary disease does not exclude pulmonary tuberculosis disease. Disease of the lung parenchyma may occur concurrently with pleural tuberculosis, and the parenchymal lung disease may not be apparent on chest radiograph due to compression of affected lung tissue by pleural fluid. For the purpose of this document, pulmonary tuberculosis refers to both disease of the lung parenchyma and pleura and laryngeal tuberculosis.

Interferon gamma release assay (IGRA) – blood tests that measure a component of cell-mediated immunity reactivity to *M. tuberculosis* in fresh whole blood.

Infection with *M. tuberculosis* – in some persons who are exposed to and who inhale *M. tuberculosis* bacteria, the bacteria are not promptly cleared by respiratory defense systems and multiply and are spread throughout the body, thereby infecting the exposed person. In most persons who become infected, the body is able to fight the bacteria to stop them from growing, further establishing a latent state. In latent infection, the bacteria are inactive, but they remain alive in the body and can become active later. In other persons, the infection with *M. tuberculosis* can progress to tuberculosis disease more promptly. *M. tuberculosis* infection encompasses both latent tuberculosis infection and tuberculosis disease.

Latent tuberculosis infection (LTBI) – infection with *M. tuberculosis* without symptoms or signs of disease manifested.

Multidrug-resistant TB (MDR TB) – tuberculosis disease caused by *M. tuberculosis* organisms that are resistant to at least isoniazid and rifampin.

***M. tuberculosis* culture** – a laboratory test in which the organism is grown from a submitted specimen (e.g., sputum) to determine the presence of *M. tuberculosis*. In the absence of cross-contamination, a positive culture confirms the diagnosis of tuberculosis disease.

Pulmonary tuberculosis – tuberculosis disease that occurs in the lung parenchyma, usually

producing a cough that lasts >3 weeks. For the purpose of this document, pulmonary tuberculosis refers to both disease of the lung parenchyma and pleura and laryngeal tuberculosis.

Pre-immigration medical screening – the medical evaluation required of all applicants.

Pre-departure screening evaluations – the medical evaluation performed within 3 weeks of departure for applicants with equivocal results (e.g., findings suggestive of tuberculosis on medical history, physical exam, or CXR, but no positive sputum smears or positive cultures). These applicants should have an evaluation consisting of medical history, physical exam, CXR, and three sputum specimens for AFB microscopy (but no cultures required) within 3 weeks prior to departure. See Appendix F.

Successfully completed tuberculosis therapy – Therapy for tuberculosis disease taken for the full duration of therapy, including the total number of recommended doses within the time frame specified in ATS/CDC/IDSA Guidelines.

Tuberculosis disease – condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early state of disease in which signs or symptoms are not present, but other indications of disease activity are present) illness. The bacteria can attack any part of the body, but disease is most commonly found in the lungs (pulmonary tuberculosis). Pulmonary tuberculosis disease can be infectious, whereas extrapulmonary disease is not infectious, except in rare circumstances.

APPENDIX C SPUTUM COLLECTIONS

Sputum Collection

- Sputum specimens of 5 – 10 mL
- Preferably early morning specimens
- Three specimens must be collected at least 24 hours apart, preferably on consecutive days
- Should be directly observed
- Applicants should rinse their mouths with purified water before providing a sputum specimen.

Sputum Specimen Transport

- Samples should be transported to the laboratory promptly
- If not transported within 1 hour, samples should be refrigerated (but not frozen)
- Ideally, specimens received in the laboratory should be processed within 24 hours of receipt
- Salivary specimens are unacceptable. The collection of a true sputum specimen is of critical importance if the organism is to be isolated.

Sputum Specimen Processing

- Sputum specimens should undergo centrifugation before smears are performed.

Use of Induced Sputum

- For patients who have difficulty producing sputum, there are several methods of obtaining a specimen. Inhalation of an aerosol of sterile hypertonic saline (3% – 15%), usually produced by an ultrasonic nebulizer, can be used to stimulate the production of sputum. Even though aerosol-induced specimens may appear thin and watery, they should be processed. **The specimen should be clearly labeled as “induced sputum” so it will not be discarded by the laboratory as an inadequate specimen.** Even when alternative methods are used, three specimens are required at least 24 hours apart, preferably on consecutive days.
- Sputum induction can be used for children as young as 3 years of age.
- A gastric aspirate specimen can be used for all ages (but sputum preferable in adults) and may be especially helpful in young children.

APPENDIX D USEFUL WEB LINKS

WHO guidance on laboratory standards:

http://www.phppo.cdc.gov/dls/ila/TB_Toolbox.aspx

ATS/CDC/IDSA treatment guidelines:

http://www.cdc.gov/tb/pubs/mmwr/Maj_guide/Treatment.htm

Francis J. Curry Center and California Department of Health Services “Drug-resistant tuberculosis: a survival guide for clinicians?”

http://www.nationaltbcenter.edu/products/product_details.cfm?productID=WPT-11

Oxford Immunotec, manufacturers of T-SPOT®: <http://www.oxfordimmunotec.com/>

Cellestis, manufacturers of QuantiFERON-TB Gold®: <http://www.cellestis.com/>

DGMQ TB TI website: http://www.cdc.gov/ncidod/dq/panel_2007.htm

International Panel Physicians Association website: <http://www.panelphysicians.org/>

WHO tuberculosis yearly report: <http://www.who.int/mediacentre/factsheets/fs104/en/>

WHO Guidance for national tuberculosis programmes on the management of tuberculosis in children: http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.371_eng.pdf

International Standards for Tuberculosis Care:

http://www.who.int/tb/publications/2006/istc_report.pdf

CDC tuberculosis: <http://www.cdc.gov/tb/>

APPENDIX E. ADDITIONAL INSTRUCTIONS FOR LARGE REFUGEE RESETTLEMENTS

The following instructions apply for refugees being resettled to the United States. In refugee emergencies, tuberculosis may not be addressed in this manner.

Refugee populations

Refugees are commonly reported to have elevated rates of tuberculosis. Because many refugees live in large camps that may have crowded living conditions, the potential exists for outbreaks of tuberculosis. Failure to appropriately screen refugees in a timely manner and failure to perform contact investigations can result in refugees with tuberculosis disease remaining undetected, which can lead to the development of outbreaks. Extremely elevated rates of tuberculosis and tuberculosis outbreaks may cause refugee movement to be stopped while control measures are implemented. Moreover, elevated rates of tuberculosis or tuberculosis outbreaks among refugees have the potential to stigmatize these groups and make successful resettlement to the United States more difficult.

Chest radiographs

Chest radiographs should be performed as soon as possible after the medical screening. Documentation of the results for the chest radiographs should be available within 1 week from the time the CXR was performed.

Contact investigations

When cases of tuberculosis are newly diagnosed, contacts should be identified and screened for tuberculosis disease within 2 weeks of diagnosis of the potential source case.

Isolation of refugees with tuberculosis

To minimize transmission to others, refugees with smear-positive tuberculosis should be relocated to an isolation area until sputum smears become negative.

Waivers

The United States is responsible for the health of refugees accepted into the United States Resettlement Program. To ensure adequate care for refugees, attempts should be made to quickly resettle children with tuberculosis disease and refugees with difficult clinical courses. For refugees who are protection cases and are diagnosed with tuberculosis disease, attempts should be made to secure a waiver upon diagnosis so the refugees may travel as soon as they are smear-negative.

APPENDIX F PRE-DEPARTURE EVALUATIONS

Additional screening immediately prior to departure (pre-departure evaluation) may be required in the event of an outbreak of tuberculosis disease or in the setting of extremely elevated rates of tuberculosis disease.

When applied, pre-departure evaluations serve as an additional measure to prevent importation of tuberculosis disease into the United States.

If the need arises, CDC will inform the Department of State and panel physicians to implement pre-departure evaluations.

When pre-departure evaluations are required, they shall be performed on applicants who are Class B1 TB, Pulmonary. The evaluations shall be performed within 3 weeks of departure. The pre-departure evaluation shall consist of a medical history, physical examination, CXR, three sputum specimens for AFB microscopy (but no cultures required).

APPENDIX G TUBERCULOSIS INDICATORS

CDC is responsible for monitoring the effectiveness and impact of these Technical Instructions to diagnose applicants with tuberculosis disease. To assist with this monitoring, the following tuberculosis indicators were developed. These statistics enable panel physicians and CDC alike to monitor the quality of these programs. CDC requests that panel physicians track these statistics and routinely report them to CDC. The frequency of reporting is based on the volume of applicants examined during a typical year:

- <5,000 applicants: report yearly (January 1)
- >5,000 applicants: report quarterly (January 1, April 1, July 1, and October 1)

CDC is available to provide technical assistance, including templates, to panel physicians compiling and reporting these statistics.

Table 2. Tuberculosis indicators to be tracked monthly

Indicator for each calendar month	Definition of indicator:
1. Number of applicants screened	
1a. Number of applicants screened	This indicator represents the total number of applicants screened for tuberculosis at the clinic for the month.
2. Number of tuberculosis suspects	
2a. CXR suggestive of tuberculosis	This indicator represents the number of applicants screened in the clinic who have CXRs indicating a possible tuberculosis condition.
2b. Signs and symptoms of tuberculosis and normal CXR	This indicator represents the number of applicants screened in the clinic who have normal CXRs BUT who have symptoms or other indications of a tuberculosis condition.
2c. HIV infection and normal CXR and no signs or symptoms of tuberculosis	This indicator represents the number of applicants screened in the clinic who are HIV-infected BUT who have normal CXRs and no tuberculosis symptoms.
2d. TOTAL	Total number of suspect tuberculosis cases for the month. The sum of 2a-2c should equal this total.
2e. TOTAL with sputum results	Total number of suspect tuberculosis cases for the month who provided sputum specimens for the month.
3. Nontuberculous mycobacteria	
3a. Smear +/NTM	This indicator represents the number of suspect tuberculosis cases whose sputum samples tested smear positive and whose culture results indicated a nontuberculosis mycobacterium.
3b. Smear -/NTM	This indicator represents the number of suspect tuberculosis cases whose sputum samples tested smear negative and whose culture results indicated a nontuberculosis mycobacterium.
3c. TOTAL	The Total number of suspect tuberculosis cases whose culture results indicated a nontuberculosis mycobacterium.
4. Extrapulmonary tuberculosis cases	
<ul style="list-style-type: none"> These cases consist of patients who are diagnosed with extrapulmonary tuberculosis disease. 	
4a. Extrapulmonary tuberculosis Cases	This indicator represents the number of applicants seen in the clinic who are diagnosed with extrapulmonary tuberculosis. NOTE: An applicant who is diagnosed with both pulmonary and extrapulmonary tuberculosis should be counted twice, once as a pulmonary tuberculosis case and once as an extrapulmonary tuberculosis case.
5. Pulmonary TB Cases:	
<ul style="list-style-type: none"> As of the reporting date, the number of pulmonary cases diagnosed among suspect tuberculosis cases screened during the reported month. 	
5a. Smears Pending	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum smear results are still unknown at the time of reporting.
5b. Smear + /Culture +	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum smears tested both smear positive and culture positive.
5c. Smear +/Culture -	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear positive but culture negative.

5d. Smear -/Culture +	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear negative but culture positive.
5e. Smear -/Culture -	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested both smear negative and culture negative.
5f. Smear +/Culture pending	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear positive and whose culture results are still unknown.
5g. Smear -/Culture pending	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear negative and whose culture results are still unknown.
5h. Smear +/Culture contamination	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear positive and whose cultures results were contaminated.
5i. Smear -/Culture contamination	This indicator represents the number of applicants screened at the clinic who were diagnosed with pulmonary tuberculosis and whose sputum samples tested smear negative and whose cultures results were contaminated.
5j. TOTAL	Total number of pulmonary tuberculosis cases for the month. The sum of 5a-5i should equal this total.
6. Drug Susceptibility Testing (DST) Results:	
<ul style="list-style-type: none"> Among pulmonary TB cases with positive cultures, these are the DST results. 	
6a. DST Pending	This indicator represents the number of pulmonary cases whose DST results are still being processed, results currently unknown.
6b. Pansusceptible	This indicator represents the number of pulmonary cases whose DST results were specified as 'pansusceptible' (susceptible to all tested drugs).
6c. INH monoresistance	This indicator represents the number of pulmonary cases whose DST results were specified as only resistant to INH.
6d. RIF monoresistance	This indicator represents the number of pulmonary cases whose DST results were specified as only resistant to RIF.
6e. MDR TB	This indicator represents the number of pulmonary cases whose DST results were specified as 'MDR TB'.
6f. XDR TB	This indicator represents the number of pulmonary cases whose DST results were specified as 'XDR TB'.
6g. Poly-resistant but not MDR TB or XDR TB	This indicator represents the number of pulmonary cases whose DST results were specified as 'poly-resistant' (resistant to many drugs) but not categorized as MDR or XDR TB.
6h. Monoresistant to a drug other than INH or RIF	This indicator represents the number of pulmonary cases whose DST results were specified as resistant to only one drug other than INH or RIF.
6i. TOTAL	Total number of DST results obtained during the month. The sum of 6a-6g should equal this total. Also, this total should equal the total number of pulmonary tuberculosis cases with positive cultures.
7. Pulmonary Tuberculosis Treatment:	
<ul style="list-style-type: none"> This indicator represents current treatment status of the tuberculosis cases diagnosed within the month being reported. 	

7a. Currently under treatment (<12 months)	This indicator represents the number of patients who are currently under treatment and have who have been under treatment for <u>less than</u> 12 months.
7b. Currently under treatment (\geq 12months)	This indicator represents the number of patients who are currently under treatment and have who have been under treatment for <u>greater than or equal to</u> 12 months.
7c. Treatment completed (\leq 12 months)	This indicator represents the number of patients who had been on treatment for <u>less than or equal to</u> 12 months and have <u>completed</u> treatment.
7d. Cure	This indicator represents the number of patients who were specified as 'cured'.
7e. Default	This indicator represents the number of patients who refused or defaulted treatment.
7f. Death	This indicator represents the number of patients who died.
7g. Transfer out	This indicator represents the number of patients who 'transferred out' to another program or to another facility.
7h. Did not register	This indicator represents the number of patients who did not register at a DMGQ-approved DOT site.
7h. TOTAL	Total number patients who have undergone pulmonary TB treatment during the month. The sum of 7a-7g should equal this total.
8. Percent of patients with culture conversion:	
8a. Percentage of patients with culture-positive pulmonary tuberculosis (excluding MDR TB/XDR TB) with culture conversion within 90 days of starting therapy for the month	This indicator represents the number of patients with culture-positive pulmonary tuberculosis (excluding MDR TB/XDR TB) with culture conversion within 90 days of starting therapy for the month, <u>divided by</u> the total number patients with culture-positive pulmonary tuberculosis (excluding MDR TB/XDR TB).
9. Pulmonary tuberculosis treatment for persons on treatment at the time of reporting:	
9a. Currently under treatment (<12 months)	This indicator represents the number of patients who are currently under treatment and who have been under treatment for <u>less than</u> 12 months in your facility/program.
9b. Currently under treatment (\geq 12months)	This indicator represents the number of patients who are currently under treatment and who have been under treatment for <u>greater than or equal to</u> 12 months in your facility/program.
9c. Default	This indicator represents the number of patients who refused or defaulted treatment in your facility/program.
9d. TOTAL	Total number of patients who have undergone pulmonary tuberculosis treatment in your facility/program. The sum of 9a-9c should equal this total.

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