Contact for more info
Dr. Neema Malhotra, M.D.
USCIS Civil Surgeon
USCIS Clinic
uscisClinic.com
(408) 684-8600

CIVIL SURGEONS

Accessible version (URL):
https://www.cdc.gov/immigrantrefugeehealth/exams/ti/civil/tuberculosis-civil-technical-instructions.html

Centers for Disease Control and Prevention
Division of Global Migration and Quarantine

CS297106-A

OVERVIEW OF TUBERCULOSIS TECHNICAL INSTRUCTIONS

The medical screening for tuberculosis among people applying for adjustment of status for US permanent residence, 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 enable civil surgeons to detect applicants who need further evaluation for pulmonary tuberculosis disease, ensure that those diagnosed are treated, and thus reduce the risk of spread of tuberculosis among the US population.

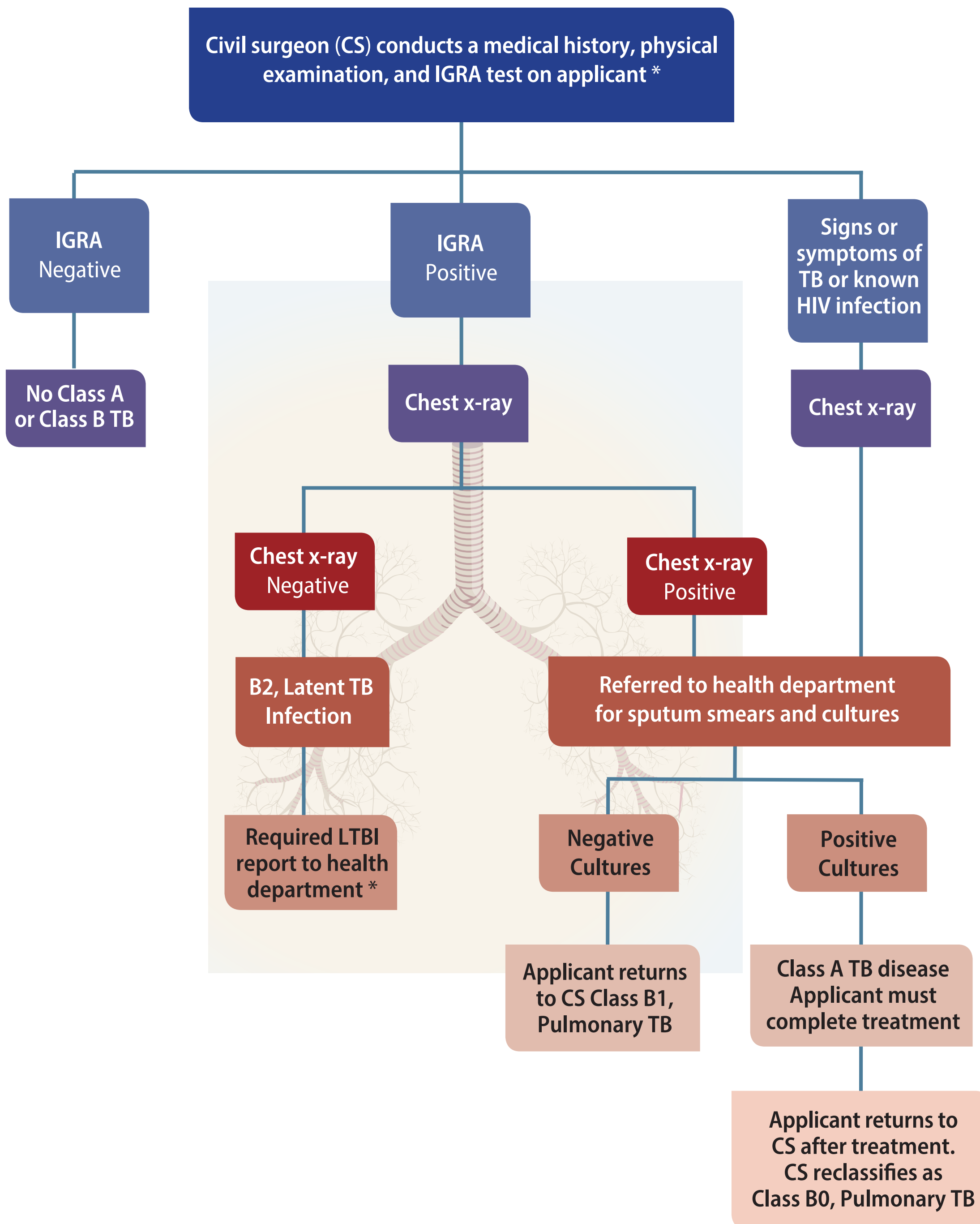
Pulmonary tuberculosis is a disease that involves the lung parenchyma and is often infectious (i.e., contagious [determined by sputum smear examination for acid-fast bacilli (AFB) and mycobacterial culture]). Laryngeal tuberculosis is rare but highly infectious. Disease of the lung parenchyma may occur concurrently with pleural tuberculosis, and the parenchymal lung disease may not be apparent on chest radiograph because of compression of affected lung tissue by pleural fluid. Because the emphasis for the status adjustment medical evaluation is on infectiousness, for the purpose of this document, the term tuberculosis disease refers to disease of the lung parenchyma, pleural tuberculosis, laryngeal tuberculosis, and tuberculosis of the intrathoracic lymph nodes. Other forms of extrapulmonary tuberculosis and latent tuberculosis infection (LTBI) are not included in the definition of tuberculosis disease for the purposes of these Technical Instructions, and are defined separately.

The Division of Global Migration and Quarantine (DGMQ) developed these instructions in consultation with US tuberculosis subject matter experts. These instructions define the specific responsibilities of civil surgeons in terms of testing and referral for purposes of US lawful permanent residence eligibility only. These instructions are specific to the status adjustment medical evaluation and must not be used as guidelines to test for or treat tuberculosis disease in other settings or as a clinical manual that defines detailed laboratory procedures or specific treatment regimen details.

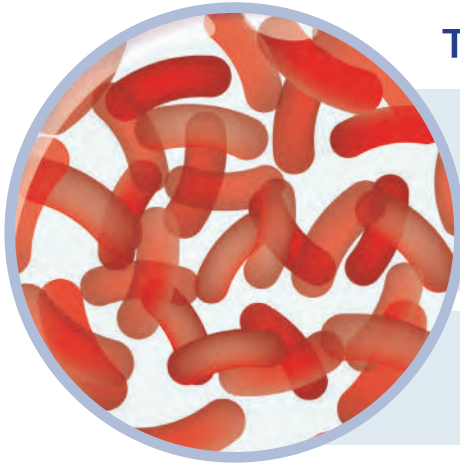
US Citizenship and Immigration Services in the US Department of Homeland Security (DHS) designates civil surgeons. Civil surgeons must perform the medical examination according to the procedures prescribed in these Technical Instructions. Civil surgeons must report all confirmed or suspected tuberculosis disease cases promptly to the health department of jurisdiction to ensure that applicants are started on the appropriate drug regimens and that thorough contact or source case (for pediatric applicants) investigations are initiated.

The instructions in this document supersede all previous Tuberculosis Technical Instructions, Updates to the Technical Instructions, memoranda and letters to civil surgeons. These instructions are to be followed for tuberculosis disease screening and treatment of all applicants.

Figure1. Civil surgeon tuberculosis screening medical examination for all applicants 2 years of age or older



* Interferon gamma release assay (IGRA), Latent tuberculosis infection (LTBI)



TUBERCULOSIS SCREENING

All applicants 2 years old or older must have an interferon gamma relsease assay (IGRA).

Tuberculin skin testing (TST) can not be used as a substitute for IGRA testing.

All applicants with a positive IGRA, known human immunodeficiency virus (HIV) infection, or signs or symptoms of tuberculosis disease, must have a chest radiograph (chest x-ray).

A complete screening medical examination for tuberculosis disease consists of a medical history, physical examination, interferon gamma release assay (IGRA) if 2 years old or older, chest radiography (chest x-ray) when required, and referral to the health department of jurisdiction when required.

All applicants <2 years of age 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 disease or have known human immunodeficiency virus infection (HIV) must have a TST or IGRA, must have a chest x-ray (anteroposterior or posteroanterior view and a lateral view), and must be reported to the health department of jurisdiction for further evaluation.

All applicants 2 years of age or older must have an IGRA performed. Current US clinical practice guidelines suggest using TST rather than an IGRA in healthy children <5 years of age for whom it is decided that diagnostic testing for tuberculosis disease is warranted; some pediatric experts use IGRA for younger children (Red Book 2018). Because of programmatic concerns in the setting of this examination, civil surgeons must use an IGRA as defined in these instructions for all applicants 2 years of age or older.

If the IGRA is positive or if the applicant has signs or symptoms of tuberculosis disease or has known HIV infection, a chest x-ray (anteroposterior or posteroanterior view and a lateral view for applicants <10 years of age; posteroanterior view for applicants ≥10 years of age) must be performed. Applicants who have chest x-ray findings suggestive of tuberculosis disease, signs or symptoms of tuberculosis disease, or known HIV infection must be referred to the health department of jurisdiction for sputum testing.

HIV testing is not a requirement of the medical screening process, however, civil surgeons may advise applicants about HIV testing for whom testing is clinically indicated. Such applicants may include those with signs and symptoms suggestive of HIV infection or those with tuberculosis disease. For such applicants, the consent for HIV testing should include the following:

- Applicants understand they do not have to be tested for HIV.
- Applicants understand that if they would like to be tested for HIV, they do not have to be tested for HIV by a civil surgeon.
- Applicants understand that civil surgeons must include the test results on the paperwork they complete.

People with HIV infection are less likely to have an abnormal chest x-ray during tuberculosis disease; and negative IGRA and TST results do not rule out tuberculosis disease, thus applicants with known HIV infection must provide sputum specimens for microscopy and culture regardless of IGRA and chest x-ray results in order to rule out tuberculosis disease.

Civil surgeons that are independent of health departments must not refer applicants to a health department for IGRA testing or chest x-ray; all IGRAs and chest x-rays ordered by civil surgeons must be performed independently of a health department.

If an applicant has a positive IGRA, and no signs or symptoms of tuberculosis disease, and a negative chest x-ray, and no known HIV infection, the applicant must receive a classification of Class B2 TB, LTBI Evaluation, and must be reported to the health department of jurisdiction.

Each aspect of the examination for tuberculosis is detailed below.

Medical History

- The medical history should focus on risk factors for tuberculosis disease, including previous history of tuberculosis disease; illness suggestive of tuberculosis disease (such as cough of >3 weeks' duration, dyspnea, weight loss, fever, or hemoptysis); prior treatment suggestive of tuberculosis disease treatment; and prior diagnostic evaluation suggestive of tuberculosis disease. The clinical expression of tuberculosis disease may be different in children than in 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.
- If the applicant was previously diagnosed with tuberculosis disease in the United States, the civil surgeon should try to get those records by contacting the appropriate state or local health department for a copy of the applicant's medical records or asking the applicant to obtain and provide those records.
- The medical history must also include inquiries regarding family or household contact with a person who has or had tuberculosis disease or illness, treatment, or diagnostic evaluation suggestive of tuberculosis disease.
- Prior receipt of bacille Calmette-Guérin (BCG) vaccination must be ascertained; review and record if documentation and date of receipt are available. 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.

Physical Exam

- Pertinent elements of the physical exam for tuberculosis disease 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.

Immune Response to *M. tuberculosis* Antigens

All applicants 2 years of age or older must have an IGRA test to determine immune response to *M. tuberculosis* antigens.

Exceptions include applicants with written documentation from a physician of a previous positive IGRA. Applicants 2 years of age and older who provide documentation of a previous positive TST must still have an IGRA performed; if the IGRA is negative, the applicant is considered to have a negative immune response to *M. tuberculosis* antigens in this examination. For past positive IGRA results, 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 offce information. Applicants with a history of positive IGRA must have a chest x-ray. If the chest x-ray is normal, the applicant has no signs or symptoms of tuberculosis disease and no known HIV infection, the civil surgeon must report that the applicant has LTBI to the health department of jurisdiction. Applicants who have documentation of previous diagnosis and complete treatment for LTBI who have a negative chest x-ray, no signs or symptoms of tuberculosis disease or known HIV infection, do not have to be diagnosed with LTBI or reported to the health department and can be classified as "No Class A or Class B TB."

- Interferon Gamma Release Assays: (IGRA)
  Interferon gamma release assays are blood tests that measure a component of cell-mediated immune reactivity to M. tuberculosis in fresh whole blood. The US Centers for Disease Control and Prevention (CDC) will only allow use of IGRA tests approved by the US Food and Drug Administration (FDA). Currently, there are two FDA-approved products: QIAGEN QuantiFERON® (any iteration approved by FDA) or Oxford Immunotec T-SPOT®.TB. Civil surgeons must follow the manufacturers' written instructions for collection of samples, performing testing, and interpreting test results. For the purpose of tuberculosis screening according to these Technical Instructions, an indeterminate test result must be

documented as indeterminate and not result in repeat testing by the civil surgeon, chest x-ray, or B2 classification. However, applicants with an indeterminate test result should be advised to have a repeat test. The IGRA test used and the results must be documented in Part 8, A. 1. of the I-693, even for those with negative or indeterminate results. Results should be available within 48 hours of sample collection.

- Tuberculin skin testing (TST)
  TST can only be used in children under 2 years of age when indicated. PPD must be administered intradermally by the Mantoux method. Ideally, preparations used should be equivalent to 5TU PPD-S. A TST is considered positive if it is ≥ 10 mm (≥ 5 mm if applicant is a known contact to a recent case of tuberculosis disease).

CHEST RADIOGRAPHY

Civil surgeons must refer applicants with abnormal chest radiographs suggestive of tuberculosis disease to the health department of jurisdiction for further evaluation.

Although findings on a single radiograph cannot confirm the diagnosis of tuberculosis disease, they do determine the need for further evaluation by the health department of jurisdiction.

A chest radiograph (chest x-ray) is required for all applicants who

- Have a positive IGRA result; or
- Have known HIV infection, regardless of IGRA result; or
- Have signs or symptoms of tuberculosis disease, regardless of IGRA result; or
- Have extrapulmonary tuberculosis, regardless of IGRA result

When performed, chest radiography must consist of a standard posteroanterior view for all applicants ≥10 years of age. Applicants <10 years of age who undergo chest radiography must have a standard anteroposterior or standard posteroanterior view and must also have a lateral view. If a child undergoes a posteroanterior view, the chest x-ray must be labeled "PA" for the benefit of the interpreting radiologist's review.

The civil surgeon must indicate on the chest x-ray requisition that there is a high suspicion of tuberculosis disease. Chest x-rays must be interpreted by a radiologist and reviewed by the civil surgeon. Documentation of the results for the chest x-rays must be available within 1 week from the time the chest x-ray was performed. Chest x-rays of any applicants must be retaken if the initial chest x-ray is suboptimal because of factors such as poor inspiration or motion artifact. Chest x-ray interpretations must include comparisons with prior chest x-rays, if available.

The radiologist must use digital radiography (computed radiography [CR] or direct digital radiography [DDR]) to obtain plain chest radiographs of applicants. Digitized analog images are not acceptable.

Digital radiography equipment systems must meet the following requirements:

- Images must be interpreted by a radiologist on a high-resolution monitor. The workstation monitors used by technologists are not adequate for image interpretation and must never be used by the radiologist for diagnosis.
    - The monitors used by the radiologists must be medical-grade and at least 3 megapixels (MP) in "display resolution" and must be advertised as appropriate for primary image interpretation (not for image review).
- Images must not be interpreted from laser-printed films, as the quality of printing varies greatly and film format cannot be optimized.
- DICOM images at least 4-5 megabytes (MB) in size must be provided to health departments to which referrals are made for evaluation for tuberculosis disease or LTBI.

Women who are pregnant and have a positive IGRA or any of the other conditions listed above are required to have a chest x-ray to adjust status. Women who are pregnant may postpone the required chest x-ray (and status adjustment medical examination) until after pregnancy but are required to have a chest x-ray to adjust status if they meet one of the above criteria. Civil surgeons must obtain consent from pregnant women before performing a chest x-ray. Pregnant women undergoing chest radiographs must be provided abdominal and pelvic protection with two lead shields that fully wrap around their abdomen and pelvis.

If a chest x-ray is required, applicants with clinical and radiographic findings suggestive of common bacterial infections of the respiratory tract may be treated with a course of antibiotics. However, fluoroquinolones must not be used for empiric treatment of respiratory infections because they are a mainstay of second-line therapy for tuberculosis disease and their use could both result in mistreatment of tuberculosis disease and lead to drug-resistant tuberculosis disease. After treatment for respiratory tract infections, the chest x-ray for medical screening must not be performed until at least 8 weeks after treatment unless the applicant's clinical status warrants further evaluation earlier than 8 weeks after treatment.

REQUIRED REFERRAL AND REPORTING TO HEALTH DEPARTMENTS

The health department of jurisdiction will determine whether the applicant has tuberculosis disease and needs treatment.

In the United States, tuberculosis disease is suffciently uncommon and its treatment is suffciently complex that only an expert must treat it. Applicants with suspected tuberculosis disease must receive their treatment from providers with considerable experience and expertise with tuberculosis patients, such as health departments or expert clinicians under contract to, or designated by the health departments. Public health departments have considerable experience in dealing with such difficult issues as patient non-adherence, drug resistance, and HIV co-infection; and most use directly observed therapy (DOT) to ensure that people with tuberculosis disease continue their therapy until completion.

For an applicant requiring referral for tuberculosis disease, the civil surgeon must not classify, issue medical clearance for tuberculosis, or sign the I-693 form until the applicant returns from the local health department with documentation of the results of his or her tuberculosis disease evaluation. Tuberculosis cultures require 8 weeks of incubation before results can be reported as negative and the applicant can receive a Class B1, Pulmonary TB classification. Positive cultures or clinically diagnosed tuberculosis disease will result in a Class A TB Classification.

All applicants with an abnormal chest x-ray suggestive of tuberculosis disease must be referred to the health department of jurisdiction for further evaluation. Applicants with clinical signs or symptoms suggestive of tuberculosis disease or known HIV infection must also be referred regardless of IGRA result or chest radiograph findings.

All applicants with extrapulmonary disease must be referred to the health department for further evaluation regardless of chest x-ray results as well. If the applicant appears very ill and tuberculosis disease is suspected, the referral must be made immediately to avoid delay in treatment. At the time of referral, include in the I-693 form the IGRA and chest x-ray results, any signs or symptoms, the approximate date of US arrival, and the reason for referral.

All applicants diagnosed with latent tuberculosis infection (LTBI) must be reported to the local health department.

Applicants with a positive IGRA result and chest x-ray not suggestive of tuberculosis disease, no known HIV infection, and no signs or symptoms of tuberculosis disease have LTBI. The positive IGRA results must be communicated to the applicant. Then the applicant's name, contact information, IGRA results, and chest x-ray results must be reported to the local health department of jurisdiction. Nationwide, health departments have different systems for managing LTBI. For this reason, civil surgeons must proactively communicate with the health department of jurisdiction to coordinate referral and reporting. For applicants who are diagnosed with LTBI, the I-693 can be completed and given to the applicant. Civil surgeons must inform such applicants that their LTBI diagnosis has been reported to the local health department and should advise the applicant that follow-up treatment is important to prevent tuberculosis disease, although not required to complete the status adjustment process.

Applicants who have documentation of being diagnosed and completing treatment for LTBI prior to the civil surgeon examination must have a chest x-ray as part of the civil surgeon evaluation. If the chest x-ray is negative and the applicant does not have signs or symptoms of tuberculosis disease or known HIV infection, the applicant does not have to be diagnosed with LTBI or reported to the health department and can be classified as "No Class A or Class B TB."

TUBERCULOSIS LABORATORY TESTING BY THE HEALTH DEPARTMENT

All mycobacteriology laboratory work must be performed by the local or state health department or by a private laboratory designated by the health department. An applicant with an abnormal chest x-ray suggestive of tuberculosis disease, signs and symptoms of tuberculosis disease, or known HIV infection must provide three early-morning fasting sputum specimens on consecutive working days within a 7-day period. The collection of the three sputa must be supervised.

All three sputum specimens must be examined for the presence of acid-fast bacilli (AFB) and cultured for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level. Positive *M. tuberculosis* cultures must undergo drug susceptibility testing (DST). When tuberculosis cultures are performed, the health department must not sign the I-693 referral section until cultures are reported as negative at the end of the 8-week incubation period, or after complete tuberculosis disease treatment with negative end of treatment culture results for those diagnosed with tuberculosis disease.

The laboratory requirements in these instructions do not prevent civil surgeons or health department laboratories from using additional molecular tests for tuberculosis disease, such as the Hain GenoType® MTBDRplus assay, the Cepheid Xpert® MTB/RIF, or the Xpert® MTB/RIF Ultra (Ultra). These molecular tests might be particularly helpful when there is a strong suspicion of drug resistance or if nontuberculous mycobacteria (NTM) is suspected. Clinical treatment decisions may be based on the results of molecular tests for tuberculosis disease. Molecular testing may augment the use of AFB smears and cultures but cannot be used to replace AFB smears or cultures to clear applicants for status adjustment.

TUBERCULOSIS TREATMENT

Any applicant diagnosed with tuberculosis disease who needs treatment must receive a classification of Class A TB and is not cleared until successful completion of treatment, regardless of the diagnostic criteria.

If the health department of jurisdiction diagnoses tuberculosis disease (either bacteriologically or clinically), the health department must treat and manage the tuberculosis disease. Health departments are responsible for ensuring that people with tuberculosis disease in their jurisdictions are promptly started on and complete appropriate drug regimens and for conducting thorough contact investigations.

A civil surgeon who is informed by the health department that a referred applicant has been diagnosed with tuberculosis disease and wishes to treat that applicant for tuberculosis disease must do so in close collaboration and consultation with the health department of jurisdiction. If a civil surgeon serves as the treating physician, treatment must be delivered as directly observed therapy (DOT).

Applicants with tuberculosis disease must be treated according to the CDC, the American Thoracic Society (ATS), and the Infectious Diseases Society of America (IDSA) guidelines, available at https://www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf.

TUBERCULOSIS CLASSIFICATIONS

For applicants requiring referral, the civil surgeon must not classify, issue medical clearance for tuberculosis, or sign the I-693 form until the applicant returns from the local health department with documentation of the results of his or her tuberculosis disease evaluation. Tuberculosis cultures require 8 weeks of incubation before results can be reported as negative and the applicant can receive a Class B1, Pulmonary TB classification. Positive cultures or clinically diagnosed tuberculosis disease will result in a Class A TB Classification.

The civil surgeon is responsible for medically examining and assigning a tuberculosis classification for each applicant. Applicants diagnosed with tuberculosis disease by the health department will need to return to the civil surgeon after treatment so they can be reclassified and cleared and the I-693 can be completed.

The following are the tuberculosis classification options:

No Class A or Class B TB

Applicants without clinical findings of tuberculosis disease, without known HIV infection, and with a negative IGRA. Applicants with a remote history of tuberculosis disease who have a negative IGRA, no current signs or symptoms of tuberculosis disease, and no known HIV infection are also assigned "No Class A or Class B TB."

Class A TB

All applicants who have tuberculosis disease. This class includes applicants who are diagnosed with tuberculosis disease by the civil surgeon and health department and applicants who present to the civil surgeon already on tuberculosis treatment at the time of their medical exam. This class also includes applicants with extrapulmonary tuberculosis who have a chest x-ray suggestive of tuberculosis disease, regardless of sputum smear and culture results.

Class B0, Pulmonary TB

Applicants who were diagnosed with tuberculosis by the civil surgeon and health department during the medical examination process and successfully completed directly observed therapy.

Class B1, Pulmonary TB

Applicants who have signs or symptoms, physical exam, or chest x-ray findings suggestive of tuberculosis disease; or have known HIV infection; are referred to the health department for additional evaluation; but have negative AFB sputum smears and cultures and are not diagnosed with tuberculosis disease.

Class B1, Extrapulmonary TB

Applicants with extrapulmonary tuberculosis, a normal chest x-ray, and negative sputum smears and cultures (if required).

Class B2 TB, Latent TB Infection

Applicants who have a positive IGRA, or history of a positive IGRA, and a chest x-ray not suggestive of tuberculosis disease. The IGRA result, the applicant's status with respect to LTBI treatment, and the medication(s) used must be documented. For applicants who had more than one IGRA, all dates and results must be documented. All of these applicants must be reported to the local health department of jurisdiction. The civil surgeon can treat these applicants for LTBI or refer them for treatment elsewhere, but the applicants do not have to complete treatment before they are medically cleared and their I-693 forms are completed, because LTBI is not a Class A condition.

Class B, Other Chest Condition (non-TB)

Applicants with an abnormal chest radiograph suggestive of disease that is not tuberculosis in an applicant with no clinical signs or symptoms of active TB.

Re-classification of Applicants after Treatment for Tuberculosis Disease

An applicant with tuberculosis disease must complete a CDC/ATS/IDSA-recommended course of tuberculosis disease treatment. When treatment has been completed, a representative of the health department must sign the "Referral Evaluation" section (Part 9.) of the I-693 form, indicating that the applicant has complied with the recommended health follow-up. When the applicant returns to the civil surgeon's office, the civil surgeon must:

- Cross out the initial Class A TB classification with a single stroke, and initial and date the change (civil surgeon must indicate that applicant was initially Class A).
- Change the applicant's status to Class B0, Pulmonary TB. If tuberculosis disease treatment has been prolonged, other portions of the medical examination may need to be repeated. When all portions of the examination are current, the civil surgeon can sign the "Civil Surgeon Certification" section of the I-693 form (Part 7. 8.), indicating that the applicant is medically cleared.
- Indicate the following information in the "Remarks" section of the I-693 form (may attach a separate sheet of paper, if needed):
    - The drug regimen used (medication names, dosages, number of doses given)
    - The date treatment began (month/year)
    - The date treatment was completed (month/year)
    - The dates and results of the most recent sputum culture tests (month/year)

Waivers

A provision allows applicants undergoing tuberculosis disease treatment to petition for a Class A waiver.

In exceptional situations, a provision allows applicants undergoing tuberculosis disease treatment to petition for a Class A waiver. Form I-601 must be completed by the applicant. These petitions are reviewed by the US Department of Homeland Security (DHS) on an individual basis and considered in situations with extenuating medical circumstances. CDC's Division of Global Migration and Quarantine reviews the application and provides an opinion to DHS regarding the case. DHS then has the final authority to approve or deny the waiver request.

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

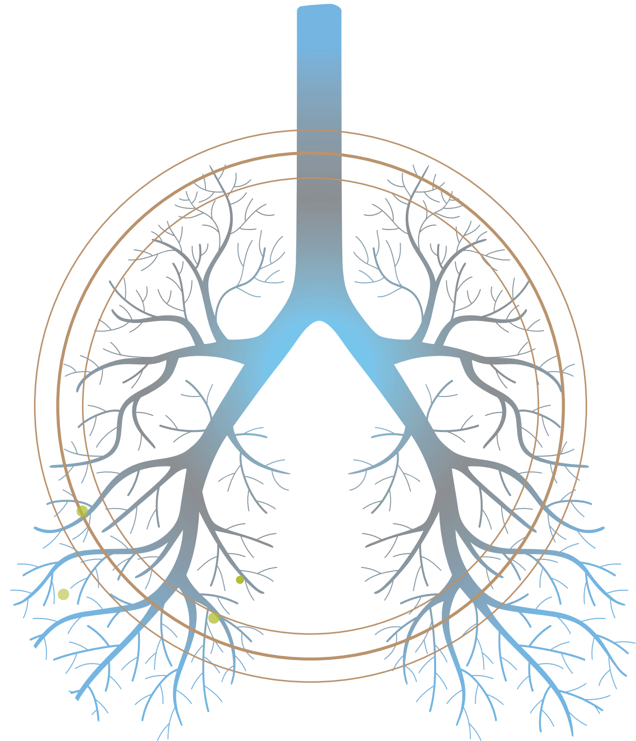
As soon as the civil surgeon is aware that an applicant applied for a Class A waiver, the civil surgeon must provide the following to CDC so that CDC can review the case and make a recommendation to DHS:

- Summary of case
- All available and pertinent laboratory results
- All chest x-ray images (in a DICOM format)

Table 1. Required referral and reporting to health departments by civil surgeons.

Requirements for Referral or Reporting to Health Departments	
Required referral to health department of jurisdiction for tuberculosis disease	▪ Chest radiograph suggestive of tuberculosis disease **OR** ▪ Signs or symptoms of tuberculosis disease **OR** ▪ Known HIV infection regardless of IGRA or TST result, or chest radiograph findings **OR** ▪ Extrapulmonary tuberculosis
Required reporting to local health department of jurisdiction for LTBI	▪ Positive IGRA but chest x-ray not suggestive of tuberculosis disease, no signs or symptoms of tuberculosis disease, and no known HIV infection

GLOSSARY OF ABBREVIATIONS



ATS	American Thoracic Society
BCG	Bacille Calmette-Guérin vaccine
CDC	US Centers for Disease Control and Prevention
Chest x-ray	Chest radiograph
DGMQ	Division of Global Migration and Quarantine
DOT	Directly observed therapy
DST	Drug-susceptibility testing
FDA	US Food and Drug Administration
HIV	Human immunodeficiency virus
IDSA	Infectious Diseases Society of America
IGRA	Interferon gamma release assay
LTBI	Latent tuberculosis infection
PPD	Purified protein derivative
TST	Tuberculin skin test

DEFINITIONS OF SELECTED TERMS

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 in person. 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. 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 resistant 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 lung parenchyma, pleura, intrathoracic lymph nodes or larynx. The presence of extrapulmonary disease does not exclude pulmonary tuberculosis disease.

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

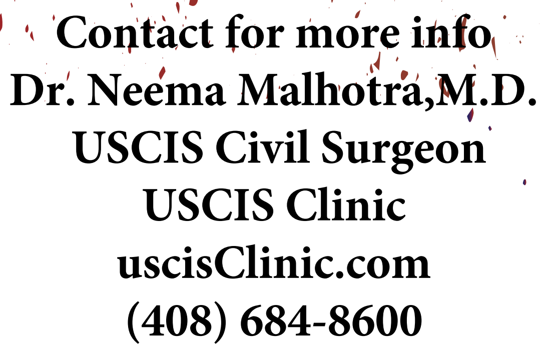
Latent tuberculosis infection (LTBI) – the presence of *M. tuberculosis* in the body without signs and symptoms, or radiographic or bacteriologic evidence of tuberculosis disease or extrapulmonary tuberculosis.

Multidrug-resistant tuberculosis disease (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.

Successfully completed tuberculosis disease therapy – Directly observed therapy for tuberculosis disease taken for the full duration of therapy, including the total number of recommended doses within the time specified in ATS/CDC/IDSA guidelines, with negative sputum smears and cultures at completion.

Tuberculosis disease – disease caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage in which signs or symptoms are not present, but other indications of disease activity are present) illness. For the purpose of this document, tuberculosis disease refers to disease of the lung parenchyma, pleura, intrathoracic lymph nodes and larynx. Latent tuberculosis infection and extrapulmonary tuberculosis are not included in this definition of tuberculosis disease.



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