UK TUBERCULOSIS TECHNICAL INSTRUCTIONS (UKTBTI)

20 AUGUST 2012 VERSION **5**

SECURING OUR BORDER CONTROLLING MIGRATION

UNITED KINGDOM TUBERCULOSIS TECHNICAL INSTRUCTIONS (UKTBTI)

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Introduction

This document serves to provide guidance to those who conduct tuberculosis (TB) screening on behalf of the government of the United Kingdom (**UK** and comprising Great Britain and Northern Ireland) under immigration legislation.

The purpose of TB screening is to detect the presence of **active pulmonary TB** amongst those who wish to apply to travel to the UK ("the Applicant"). Screening will normally relate to those who intend to stay in the UK for over six months and are travelling from a country identified by the World Health Organization (WHO) as having a high incidence of TB. However, the UK immigration authorities may, on occasion, require screening of others seeking permission to travel to the UK.

TB is a condition caused by infection by a member of the *Mycobacterium 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. Applicants will be screened by clinics on behalf of UK authorities for **active pulmonary TB**. Where other forms of TB are diagnosed, the applicant should be advised in clear terms of the need to seek medical assistance.

This programme of screening is co-ordinated on behalf of the UK by Panel Physicians (**"**Physician(s)") who have been nominated by the UK authorities. These Physicians may also have been nominated for screening purposes by the UK's international partners and/or the International Organization for Migration (IOM) acting on behalf of the UK authorities.

International collaboration

The UK is working in collaboration with a number of international partners. These currently include the IOM, the USA (Centers for Disease Control and Prevention) (CDC), Australia (Department for Immigration and Citizenship), Canada (Canadian Immigration and Citizenship) and New Zealand. In many instances, Physicians will act on behalf of a number of partners. In all circumstances, however, Physicians must provide full co-operation in working with the UK's partners. This may include the provision of data and data collections, access to facilities and oversight of screening, screening facilities and medical records for health protection, audit, quality assurance and training purposes.

Panel Physician

The Physician will abide by the conditions agreed with the UK authorities. The Physician will commission and oversee the TB screening programme in accordance with these instructions and best practice as specified by the WHO. This will entail ensuring through screening, that the Applicant is free from active pulmonary TB. Where there are no grounds to believe that active pulmonary TB pertains, the Physician will certify the clearance of screening through the issue of a Certificate ("the Certificate").

Where x-ray results or clinical observations require, the Physician will oversee sputum smear and culture testing in accordance with these instructions that have been developed in line with WHO specifications and best practice and certify clearance when appropriate. No clearance will be provided where active pulmonary TB is detected. In instances where active pulmonary TB is detected, the Physician must ensure that the Applicant is given clear and unambiguous advice about the need to seek treatment immediately through prompt advice and counselling. Where required to do so, the Physician must also report the diagnosis of active pulmonary TB to the local, regional or national authorities in the home nation and record this fact.

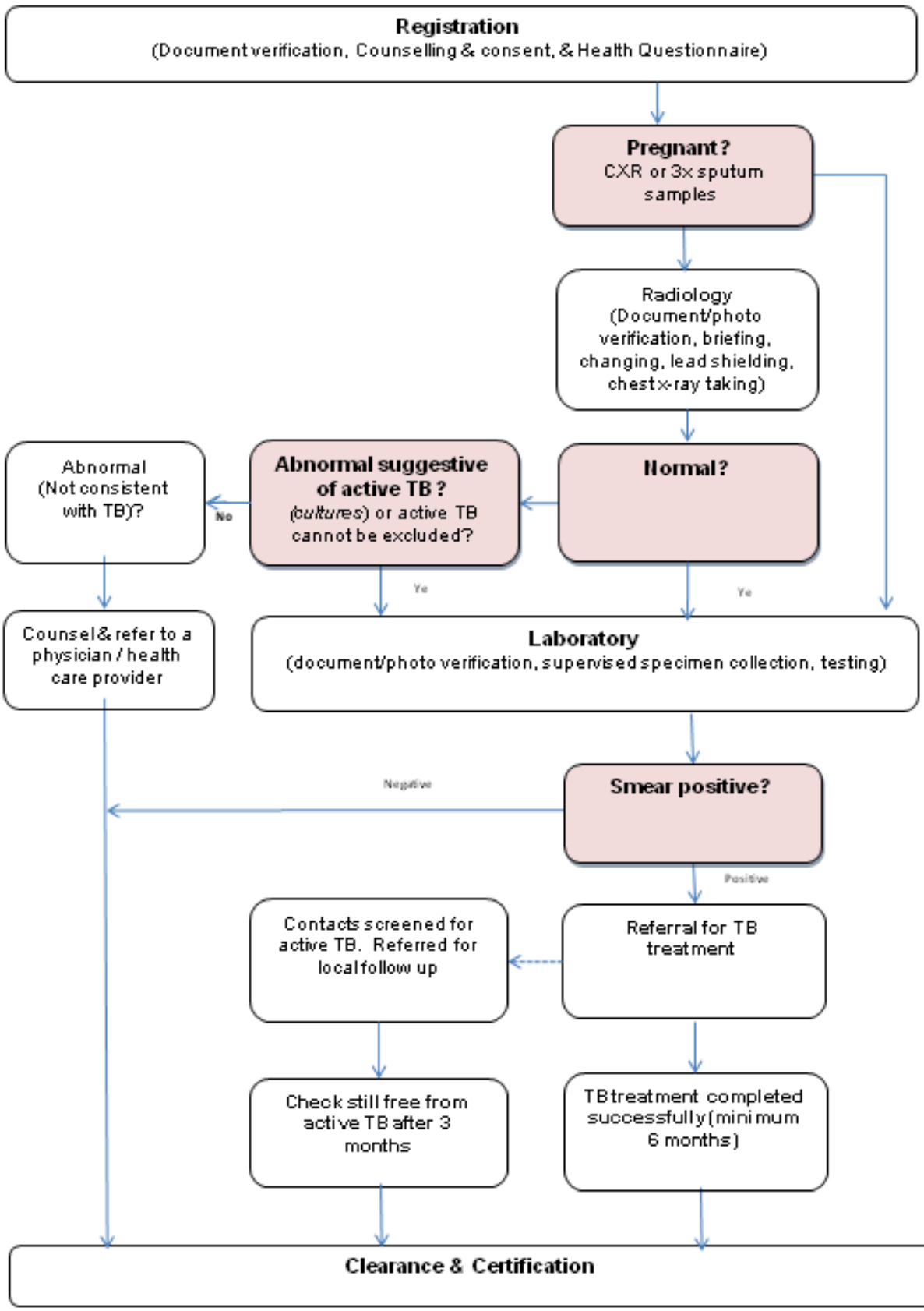
Definition of active pulmonary disease.

Diagnosis of active pulmonary tuberculosis should include:

a. Culture confirmed tuberculosis in a person with symptoms, signs or chest x-ray findings (*see Annex A) consistent tuberculosis in whom *M. tuberculosis* has been detected using sputum culture for mycobacteria for six weeks in liquid media or eight weeks in solid media with confirmation by DNA technology at least to *M. tuberculosis* level (with or without a positive smear).

b. Clinically confirmed tuberculosis where the clinician has chose to treat the patient with a full course of antituberculosis treatment in a person with an abnormal chest x ray supported by other evidence of tuberculosis such as pathology findings consistent with TB disease such as caseating granuloma, signs and symptoms consistent with pulmonary disease and/or sputum or tissue smear positive for acid fast bacilli.

UK TB SCREENING Flowchart



An Outline of the Tuberculosis Screening Process

The screening process for active pulmonary TB commences with chest x-ray (CXR). Applicants who have a CXR with findings suggestive of pulmonary TB or otherwise have signs and symptoms of pulmonary TB or who are unable to have a CXR because of pregnancy or because it is otherwise unsafe for them to have a CXR, should provide three sputum specimens to undergo microscopy for acid fast bacilli (AFB) and culture for mycobacteria and confirmation of the *Mycobacterium* species, at least to the *M. tuberculosis* complex level at a laboratory designated by the UK, its international partners or the IOM for this purpose. Applicants under 11 years of age will not normally be required to have a CXR. However, a child under 11 should have a health questionnaire completed on their behalf (see Annex E) and undergo a simple risk assessment to determine whether they are at risk of pulmonary TB. Where they fulfil one of the following criteria; is symptomatic or has physical findings of active pulmonary TB or has a history of recent contact with a case of active pulmonary TB, the Physician shall have discretion to carry out a CXR followed, where required by laboratory testing or limiting screening to the laboratory tests. Physicians should also consider undertaking a medical history and physical examination of these Applicants under 11 years of age.

The TB Screening Process

1. Consent for Screening

Applicants should be able to schedule an appointment within a reasonable timeframe, preferably within a few working days. An appointment must be made within 10 working days.

Each Applicant shall be briefed on the purpose, nature and extent of the TB screening process. This may initially be through the use of information leaflets. The Applicant must complete an Informed Consent Form in a language that they understand (or steps taken to ensure they understand). The form (Annex D) must be signed by the Applicant before the screening process starts. Where the Applicant has not reached the age of majority for the country concerned or lacks the mental or other capacity to understand and sign the form, the form must be signed by their parent or guardian. The Physician must retain the Informed Consent Form for three years and, upon request, make the form available to the UK authorities or those they direct.

Where Applicants consist of family members who are intending to travel together, the Physician shall put in place a screening process that allows the family members to be screened together. Physicians are also to consider and accommodate the need for screening using same sex personnel. Applicants with children under 11 years of age must bring those children with them to the appointment in order that the Physician can assess whether the child needs to be screened.

2. Chest Radiography

Applicants of 11 years of age and above should receive a standard posteroanterior view CXR in accordance with Annex A. Chest radiographs should be interpreted by a radiologist and reviewed by the Physician. Documentation of the results of the CXR with adequate non-removable labelling, including full name, date of birth (or such other unique identifier as the UK authorities shall prescribe), date of examination and view, should be available within one day from when 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. The Applicant should not leave until the radiologist is satisfied with the film and that no further CXR angles are warranted. Further detail of the radiological process is contained in Annex A.

In interpreting the results of the CXR, for the purposes of any subsequent treatment and to monitor disease progression, the radiologist shall be entitled to compare the results of the current CXR with any previous CXR taken for that Applicant either in respect of this or any previous entry clearance application for the UK or for any of the international partners as previously mentioned.

For Applicants below the age of 11, TB screening is not envisaged unless testing is considered appropriate (as outlined in page 6). It will be considered appropriate when the child is symptomatic of active pulmonary TB, is under treatment for TB or chronic respiratory disease such as cystic fibrosis, has previously had thoracic surgery, has cyanosis, respiratory insufficiency that limits activity or a medical history of TB or has shared with a TB infected person the same enclosed air space or household or other enclosed environment for a prolonged period (days or weeks). The health questionnaire (Annex E) shall be used in this process. Where screening is considered appropriate, e.g. when one of the three questionnaire questions is answered in the affirmative, the Physician shall have discretion to carry out a CXR followed, where required, by laboratory testing. If a child receives a CXR, the CXR should be labelled “PA” for the benefit of radiologist’s review. As well as PA, children aged under 11 should also have a lateral film.

When the Applicant aged under 11 is to be screened for TB, the Physician should consider undertaking a review of an Applicant’s medical history and consider undertaking a physical examination in circumstances where there appears to be indication of the risk of active pulmonary TB.

Any medical history or examination should focus on risk factors for active pulmonary TB, including previous history of TB; illness suggestive of TB (such as cough of two weeks’ duration, dyspnoea, weight loss, fever, or haemoptysis, unintended weight loss); prior treatment suggestive of TB treatment; and prior diagnostic evaluation suggestive of TB. The clinical expression of TB may be different in children than adults, and for children may only include generalised findings such as fever, night sweats, growth delay, and weight loss. Physicians should be aware that children are more prone to extrapulmonary TB, such as meningitis, and disease of the middle ear and mastoid, lymph nodes, bones, joints, and skin.

Any medical history should also include inquiries regarding family or household contact with a person who has or had TB or illness, treatment, or diagnostic evaluation suggestive of TB.

The CXR is the preferred screening tool for active pulmonary TB. Other tests for active TB, such as serological assays or Polymerase Chain Reaction, and for latent TB, such as Mantoux test or Interferon Gamma Release Assay (Quantiferon-TB Gold in Tube or Tspot TB), are not acceptable alternatives in terms of identifying active pulmonary TB, even when the Applicant is prepared to pay for such tests. Prior receipt of Bacille Calmette-Guérin (BCG) vaccination will not change the screening requirements or the required actions.

CXR can cause difficulties for pregnant Applicants or those for whom it is unsafe to have a CXR. Where the clinic has within three months previously taken a CXR for that Applicant either in respect of a previous entry clearance application for the UK or for any of the international partners as previously mentioned, then that CXR may be used instead of a new CXR at the radiologists discretion, e.g. when the Applicant is now pregnant. Pregnant Applicants have the option of having a CXR with extra protection, including double wrap-round shielding. Those Applicants unwilling to undertake CXR and Applicants unable for medical reasons to have a CXR must provide sputum specimens in a designated laboratory for smear and culture (see laboratory section).

Applicants whose CXR is free of any radiological result compatible with active or old pulmonary TB shall be issued with a Certificate by the Physician allowing them to proceed with their entry clearance application.

Those Applicants with any radiological result compatible with active or old TB e.g. fibrosis, infiltrate, cavitation or pleural effusion and Applicants with haemoptysis (coughing up blood) shall not be issued with a Certificate and shall proceed with laboratory testing.

Physicians must consider their duty of care to the Applicant when findings are indicative of other respiratory disorders e.g. cancer, emphysema or bronchiectasis and should consider counselling and/or referring the Applicant as appropriate. Providing the CXR is free of any radiological result compatible with active or old pulmonary TB, the Certificate may be issued without laboratory referral. However, the Certificate for such Applicants shall be completed by the Physician to indicate that the CXR was abnormal and a sputum test was not done. Where possible, a copy of the CXR and an x-ray interpretation completed by the Physician to describe the CXR result and diagnosis shall be given to the Applicant.

Laboratory testing for active pulmonary TB may only take place in laboratories which have been accredited for that purpose by the UK, IOM or the international partners. Where there is not an accredited laboratory in the country of CXR testing, those with a radiological result compatible with active or old TB shall repeat their CXR test after three months from the date of the original test. The results of the two CXRs shall then be compared by the Physician who shall only issue the Certificate when there is no evidence of disease progression.

3. Laboratory Testing

Laboratory examination for TB disease should be undertaken in a designated laboratory and must consist of at least three sputum specimens. All specimens (i.e. CXR changes indicate either active or inactive pulmonary TB) must undergo microscopy for AFB through an auramine stain and must also be examined as a culture on liquid and solid media for mycobacteria and confirmation of the *Mycobacterium* species through DNA technology, at least to the *M. tuberculosis* complex level.

Where culture specimens are reported as negative they should have been cultured for a minimum of six weeks in liquid media and eight weeks in solid media, unless a positive result is obtained earlier, in order to ascertain negativity, with a final report produced within ten weeks of collection. Positive cultures need to be reported to the Physician as soon as the results are known.

Designated laboratories will have been identified and certified by this programme or through one of our international partners, generally the CDC or the IOM and will be subject to quality assurance. Samples should be securely and promptly transported to the designated laboratory with appropriate provision around cool-chain. Applicants should not be allowed to transport specimens. If not transported within one hour, samples must be refrigerated (but not frozen). When received by the laboratory, specimens ideally should be processed with 24 hours of receipt.

Panel Physicians must either perform the specimen collection on site or arrange for it in a designated laboratory. If the Physician delegates this procedure to a nurse or phlebotomist, the Physician remains accountable for the integrity of this part of the screening procedure. Further detail of the screening procedure is also contained in Annex B.

Applicants unable to produce sputum specimens are required to have alternative methods of sputum collection performed (e.g. early morning gastric aspirates) in order that their TB status may be determined. If necessary, this can be facilitated through a new appointment. Sputum must not be collected from home. Following a second appointment (at which the Applicant attends) when the Applicant is unable to produce a sputum specimen, the Applicant shall repeat their CXR after three months from the date of the original test. The results of the two CXRs shall then be compared by the Physician who shall only issue the Certificate when there is no evidence of disease progression.

Positive *M. tuberculosis* cultures shall undergo drug susceptibility testing (DST) in the designated laboratory for isoniazid, rifampin, ethambutol, pyrazinamide, and streptomycin. 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 in the designated laboratory on second-line TB 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-aminosalycilic acid.

In addition to the recommendations provided, Physicians may use their clinical judgment in the evaluation and treatment of the Applicant. Any Applicant for whom the clinical suspicion of active pulmonary TB is high enough to warrant treatment for active pulmonary TB e.g. because of the CXR result, despite the laboratory results, is considered to have active pulmonary TB disease and shall not be issued with Certification. Subject to this exception, Applicants whose laboratory test results are free of any finding compatible with active pulmonary TB shall be issued with a Certificate by the Physician allowing them to proceed with their entry clearance application. Those Applicants with any finding compatible with active pulmonary TB or refuse to start or complete the screening process shall not be issued with a Certificate. Where the Certificate is to be issued after sputum testing, the Certificate must record this fact. The Physician must also report these cases where a Certificate is issued to the UK immigration authorities as they shall direct.

4. Referral for Treatment

No Certificate shall be provided when active pulmonary TB is diagnosed. When active pulmonary TB is detected, the Physician must ensure that the individual screened is given clear and unambiguous advice about the need to seek treatment immediately and is provided with a TB treatment referral letter (samples are contained in Annex D). Where required to do so, the Physician must also report cases of active pulmonary TB to the local, regional or national authorities in the home nation in accordance with any national protocol. The Physician must also report these cases to the UK immigration authorities as they shall direct.

The Physician shall be under no obligation to treat the Applicant. However, where the Physician agrees to carry out such treatment, such treatment shall accord with Annex C and WHO treatment standards along with any national TB protocol, using only quality assured drugs in accordance with the WHO Global Drug Facility for first-line drugs and the International Dispensary Association or WHO Green Light Committee for second-line drugs.

Upon successfully completing the treatment, but not within six months of the original examination, the Applicant may restart the screening process by providing to the Physician a written treatment summary from the treating provider. The screening process shall be repeated at an additional fee (the standard test fee) to the Applicant, and upon the Physician determining that the Applicant no longer has active pulmonary TB, a Certificate shall be issued to the Applicant together with the most recent x-ray certificate or, where this is not available, with a radiology report. In making this decision, the Physician shall compare the CXR taken at this application with the CXR taken at the previous application. The Physician shall obtain from the Applicant the name, address, date of birth and nationality of the Applicant together with a contact address in the UK (e.g. address of accommodation, educational establishment, employer or sponsor).

For those Physicians providing treatment under Directly Observed Therapy (DOT), please refer to guidance issued by the CDC.

5. Costs

The Applicant shall be responsible for the cost of the screening process, including but not limited to the administration, counselling, examination, x-ray and laboratory testing and diagnosis and, where relevant, the issue of the Certificate or referral for treatment. It shall not include the cost of any treatment for active pulmonary TB. All Applicants shall pay the same amount for the screening provided under this programme in that clinic save for pregnant Applicants who opt to provide sputum specimens rather than have a CXR who may be charged an extra amount. The amount charged shall be in line with the accepted standards of the examination country but shall not exceed the sum (if any) set by the UK authorities. The Physician shall inform the UK authorities (as advised) the full charge they intend to claim from the Applicant including any disbursements, and immediately inform the UK authorities of any variation.

When the Physician treats the Applicant in accordance with Annex C, the amount charged shall be in line with the accepted standards of that country, is fair and reasonable and not in excess of prices charged to the general public in that country for services which are the same or similar to that being provided for the Applicant.

6. Certificate, Management and Fraud

A Certificate shall be issued to all Applicants who the Physician determines as not having active pulmonary TB. The Certificate shall be valid for six months from the date of the CXR. Those Applicants with an abnormality suggestive of active pulmonary TB in their CXR result shall be provided with a copy of the CXR, or where this is not available, a radiology report, a medical form and a relevant referral letter (Annex D). The Physician shall retain securely the original CXR together with a copy of the medical form and a copy of the referral letter for three years and make them available to UK authorities or as they direct.

When a family member has active pulmonary TB, Certificates issued to all other family members of that family or others who have shared with the infected Applicant the same enclosed air space or household or other enclosed environment for a prolonged period (days or weeks) who do not have active pulmonary TB and who still intend to travel to the UK shall be issued with a Certificate with a validity period of three months and not six months.

The Physician shall also provide to the UK authorities test results, including such personal data as the UK authorities may require to identify the Applicant and to contact the Applicant in the UK, as the UK authorities shall direct.

Supervision and identification of the Applicant must be carried out by appropriate staff of the Physician at the following stages of the screening process: registration, medical examination (if performed), CXR, sputum collection and Certificate issue or treatment referral. The inspection must involve the Applicant's valid passport. At each stage, the inspector must take all reasonable steps to check the validity of the Applicant's passport, or other document(s), satisfy themselves that the photograph is of the applicant, that any date of birth in the document is consistent with the

appearance of the Applicant and that the Applicant is the rightful owner of the document. The official signature from the document may also be used for additional identification. The laboratory shall take all appropriate steps to ensure that the samples are transported, stored and tested and examined correctly and that they are clearly labelled as belonging to the Applicant. When there are doubts as to the identity of the Applicant, the Applicant shall be requested to provide further documents to substantiate his or her identity. When the Applicant's valid passport is not available, e.g. it is in the possession of the UK authorities or where there are still concerns over the identity of the Applicant, the Physician shall seek further advice from the UK immigration authorities.

All parts of the screening process must be covered by comprehensive medical insurance and all clinical participants must observe the professional obligations and codes of practice of the country in which they work and maintain their medical registration. The Physician remains responsible for the TB screening process, and checking the identity of the Applicant including such processes that are undertaken by others (e.g. laboratory testing). The Physician is also responsible for ensuring that the most up to date version of these Technical Instructions is adhered to. The UK authorities, or others that they authorise or direct, may visit, audit and evaluate the processes and protocols of the Physician, the screening process and the laboratory site. In this respect, the UK authorises the following international partners to act in such capacity on its behalf; the International Organization for Migration, the USA (Centers for Disease Control and Prevention), Australia (Department for Immigration and Citizenship), Canada (Canadian Immigration and Citizenship) and New Zealand Immigration authorities.

The UK Border Agency acknowledges the assistance and co-operation provided by the Health Protection Agency in the UK together, with the International Organization for Migration, the USA (Centers for Disease Control and Prevention), Australia (Department for Immigration and Citizenship), Canada (Canadian Immigration and Citizenship) and New Zealand. The UK Border Agency also acknowledges the summary of key quality control aspects for radiologists provided by Dr R.N. Bowry (Kenya), for the Department of Immigration and Citizenship, Australia.

Annex A: Radiological Technical Detail

Radiological suites must have adequate and well maintained radiological equipment, appropriate self-protective equipment, radiation safety guidelines, abdominal shielding and facilities to protect patient privacy when Applicants are required to dress/undress including the use of an adequate curtain or screen and gown. It is preferable that they have provision for the safe-keeping of the Applicant's possessions.

1 Radiographic techniques

- All CXRs should be taken in the Posteroanterior (PA) projection to reduce cardiac magnification.
- In a correctly exposed film, the penetration should be such that one should be able to see the first four (4) vertebral bodies well (T1-T4), and the ribs, while the rest of the vertebrae should be just visible through the heart shadow.
- In an over-penetrated film, faint soft tissue lesions can be easily missed.
- In an under-penetrated film, pulmonary infiltrations can be over-diagnosed.
- If there is a slight over-penetration, a bright spotlight should be used to examine the radiograph.
- Routine CXRs should be taken in full inspiration. This lowers the diaphragm to the level of the 10^{th} or 11th rib posteriorly.
- The position of the patient should be such that the medial ends of the clavicles are equidistant from the spinous processes of the thoracic vertebrae.
- Rotation of the chest can make the side nearer to the film appear less translucent.
- The scapulae should be clear of the lung fields.
- The CXR beam should be centred at T5 or T6 vertebral body.
- The distance of the CXR tube to the film should be 6 feet (150 cm).
- All CXRs should include costophrenic angles.
- Apices should be clearly seen (without overlying clavicles).
- If the lungs are of different translucencies one should consider:
  - Rotation,
  - Poor screen/film contact in the cassette and
  - Absent breast.
- Ensure that the following artefacts are excluded:
  - Braided hair overlying the apices can mimic a lesion,
  - Development artefacts,
  - Static marks,
  - Dirty screens,
  - Nail marks and
  - Foreign bodies in cassettes.

  o When there is constant difference in the translucency between the right and left side of the CXR, ensure that the filter in the tube assembly is correctly positioned.

2 Special views

- An apical lordotic view should be done for suspicious opacities over ribs, clavicles or other structures and a lateral decubitus view for costophrenic angle blunting to exclude pleural effusion.
- For children under 11 years of age, lateral views should be done in addition to PA view

3 Radiation safety

Please observe:

- Routine use of lead shielding for all applicants and double shielding for children and pregnant women.
- Selection of correct film size.
- CXR beam collimation (narrowing of the beam so that only the target area is exposed).
- Not performing additional CXRs or scans unless clinically indicated or requested by the UK or its international partners.

4 CXR image identification

- The CXR image must bear the date of the CXR, applicant's name in English, and name of clinic. The passport number should be included. The Gregorian calendar should be used.

5 Women

- It is common to request CXR for women of reproductive age (some of whom will be unknowingly pregnant at the time of the CXR). Panel radiologists have an ethical obligation to ensure that these applicants are adequately protected, using double wrap around abdominal and pelvic shielding when appropriate. Please be vigilant in avoiding unnecessary radiation exposure.

6 Children

- Radiation exposure should be kept to a minimum. Film size should be adequate to include the chest only.
- Abdominal shielding and correct collimation should be used.

7 Film examinations and reports

- The CXR film is to be read by the panel radiologist. The correct name, date and anatomical side markers should be included. Look at the so-called 'hidden' areas:
  - Behind the heart,
  - Apices,
  - Costophrenic angles,
  - Both hila,
  - Paratracheal regions, and

- Below the diaphragms.

- Sometimes a nodule in the lower zones may be difficult to differentiate from a nipple shadow. Repeat CXR with nipple markers to confirm. The extent and likely activity of any disease present should be described and any necessary further investigations recommended. Radiologists should report all abnormalities in the CXR film and their possible interpretation and cause.
- **If significant abnormalities, such as changes suggestive of active pulmonary TB, are detected, the radiologist should refer, or advise the Physician to refer, the applicant to an appropriate specialist immediately.**
- Ongoing failure to undertake radiology appropriately is considered improper professional practice, and may be grounds for removal.

8 Requirements of examining radiologists

Panel radiologists must ensure:

- They duly accurately record date and place of examination.
- The panel radiologist's name appears clearly.
- The results of their radiological examination are recorded fully and in consideration of the examination and any additional investigation which may have been performed.
- The radiologist acknowledges responsibility for the integrity and quality of the radiological examination process. The UK and its international partners randomly audits all radiological examinations and any evidence of failure to maintain integrity and quality of the examination will result in closer scrutiny of the radiologist and possible removal from the panel.

9 Radiographic findings which may indicate TB

Minor findings (occasionally associated with TB infection)

- **Solitary Granuloma** (< 1 cm. and of any lobe) with an **unremarkable hilum**
- **Solitary Granuloma** (< 1 cm. and of any lobe) with **calcified / enlarged hilar lymph nodes**
- Single / Multiple **calcified pulmonary nodules / micronodules with distinct borders**
- **Calcified pleural** lesions
- Costophrenic Angle **blunting** (either side **above the horizontal**)

Findings sometimes seen in active TB (or other conditions)

- Notable apical pleural capping (rough or ragged inferior border and/or ≥ 1cm thick at any point)
- **Apical fibronodular / fibrocalcific** lesions or apical **microcalcifications**
- Multiple / single **pulmonary nodules / micronodules (noncalcified or poorly defined)**
- Isolated **hilar or mediastinal mass/lymphadenopathy** (noncalcified)
- **Single / multiple pulmonary nodules / masses ≥ 1 cm."**

- Non-calcified **pleural fibrosis** and / or **effusion**.
- Interstitial fibrosis/ parenchymal lung disease/ acute pulmonary disease
- **Any cavitating lesion OR** “fluffy” or “Soft” lesions felt likely to represent **active TB**

Annex B:

Correct sputum collections will entail

- Confirming the identity of the applicant (see above).
- Explaining the collection procedure to applicants.
- Using appropriate disposable equipment.
- Safe storage and disposal of clinical waste including any sharps.
- Accurate specimen identification using non-removable labels.
- Incorporating appropriate security or coding procedures into the testing process for specimens and laboratory requests as the UK authorities shall indicate.
- Ensure all pathology test kits are within expiration dates.
- Refrigeration of specimens or transportation to the laboratory within one hour;
- Maintenance of specimen integrity during storage.
- When necessary, ensure secure transportation (including the container) with a laboratory request for specimens. Specimens should not be given to the applicant for transport.
- Participation in external quality-assurance programmes.

Sputum Collections[1]

- Sputum specimens of 5 – 10 ml.
- Preferably early morning specimens.
- Three specimens must be collected at least 24 hours apart, preferably on consecutive days.
- Must be supervised in the clinic or laboratory in a safe environment and not brought from home.
- Applicants should rinse their mouths with purified water before providing a sputum specimen. **Check sputum collected, not just saliva.**
- The collector or the supervisor of the laboratory or the laboratory technician preparing the specimen can discard any specimen found to be saliva and not sputum. In this case the applicant needs to return the following day for collection.
- A specimen of saliva must **never** be accepted as a sputum specimen. This will result in a false negative report.
- Sputum should not be induced. All applicants need to be instructed to take three deep breaths, and on the forth deep breath to cough. The cough should use an abdominal contraction and not be just from the upper chest or throat.
- The collector needs to listen to the applicants coughing to ensure that the cough comes from the stomach and not from the chest or throat. If an applicant continues to cough from the throat or is unable to cough from the stomach, they should be asked to return the following day.
- Applicants must not clear their nasal passages into the back of their throat and present this as sputum specimen.

1 CDC Technical Instructions for Tuberculosis Screening and Treatment : Using Cultures and Directly Observed Therapy, 2009

Specimen Handling

- The collector should be wearing an appropriate mask and well fitting gloves during the collection process.
- Specimens should be sent to the laboratory in a metal container with a lid that can be sealed. All specimens need to arrive at the laboratory within 4 hours of collection.
- If transport to another place is required specimens should be sent as soon as possible in a cold container. An esky, coolman, or other type of cold container containing ice packs.
- Specimens must **never** be pooled.
- Specimens must be kept below 25 degrees centigrade if being transported to another site.
- Specimens should be in a rack to prevent spillage and be protected from heat at all times. Specimens must never be frozen.

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.

Safety Measures

- It is preferred that collection take place outside in a sunny, well ventilated situation. The place should be private and free on passersby and onlookers to protect the privacy of the applicant.
- The waiting area should be away form the collection area and applicants be allowed to sit before collection and to read the collection technique instructions.
- There should be adequate crowd control and applicants must not crowd the staff at the reception area.
- All collectors must wear appropriate masks (not surgical masks) and well fitting gloves for the process.
- If specimens must be collected inside, they must be collected in a booth or room with negative airflow. There should be 12 to 18 complete room air changes per hour are required. The ventilation system must remove 12 to 18 complete room volumes of air per hour.

- A small strip of single layer tissue paper can be placed on the door of the booth, if the paper moves at 45 degrees to the door, then adequate ventilation is provided. The tape needs to be kept there for daily check on negative air flow.
- Disinfectant solutions based on phenol or alcohol can be used to disinfect the surfaces in the booth.
- Ultra violet light can also be used provided that it is cleaned once a week to prevent dust build-up and that the wavelengths of 254 nm are emitted. The UV light needs to be on for one hour after work has finished in the booth. It must be noted that this only disinfects the surfaces in the booth and benches should be kept to a minimum area, and the booth must be free of all other materials.

Annex C:

Treatment Technical Detail

Patients should be treated according to WHO guidelines.

All newly diagnosed patients with active pulmonary TB should receive a regimen containing six months of rifampicin. This should consist of two months of daily intensive phase with isoniazid, rifampicin, pyrazinamide and ethambutol followed by a further four months of a three times weekly continuation phase of rifampicin and isoniazid (2HRZE/4HR). Each dose should be observed.

Three times weekly dosing throughout therapy [2(HRZE)/4(HR)] may be used as another alternative to the regimen with a daily dose described above provided that every dose is directly observed and the patient is NOT living with HIV or living in an HIV-prevalent setting. Patients known to be infected with HIV should have a daily dose regimen at least during the intensive phase.

Where Central Nervous System tuberculosis is also diagnosed, patients should receive a minimum of 12 months of treatment.

Directly observed therapy should consist of the physical observation of the intake of each dose of the prescribed drug by an approved treatment supporter (this should be a health worker, or a trained and supervised member of the community or family).

All patients with culture confirmed tuberculosis would have drug susceptibility tests undertaken in a quality assured laboratory. Subsequent treatment of persons found to have rifampicin resistance or multi drug resistant tuberculosis (MDR TB) should be undertaken by physicians with experience of managing MDR TB.

In accordance with WHO protocols, smears are to be repeated at the end of the intensive phase for patients who had an initial positive smear. This should be repeated at three months if the two month smear is positive and drugs altered based on the results of the drug susceptibility tests which should be available at three months.

Physicians are recommended to note and follow the guidance available on the USA CDC website in relation to treatment regimes.
http://www.cdc.gov/tb/publications/guidelines/Treatment.htm

Annex D:

UK UNITED KINGDOM PRE ENTRY TUBERCULOSIS SCREENING PROGRAMME

Name:	
Date of birth:	
□ Male	□ Female
Location:	

Applicant's Declaration:
I understand that:

a. I am required to undergo testing for pulmonary tuberculosis (TB), involving an X-ray and possibly sputum tests, prior to applying for entry clearance to go to the UK;

b. In the event of pregnancy or possible pregnancy:
1. If I am pregnant, I will be offered a chest X-ray with protective shield, or the option of producing sputum for smear testing.
2. I acknowledge that submitting to a chest X-ray may involve health risks for pregnant women and that I am advised to consult a radiologist to determine and understand the risks before I take a chest X-ray. If I decide to submit to an X-ray, this shall be at my own risk only.

c. If my chest X-ray is abnormal, I will receive individual counseling and an explanation of the further testing procedures.

d. If my chest X-ray is abnormal, presenting changes compatible with tuberculosis, regardless of whether radiological findings suggest active or inactive process, I will be asked to produce sputum for smear testing.

e. If my chest X-ray is abnormal, presenting changes suggestive of an active TB process, or if there are other clinic reasons for concern, then in addition to

sputum smear I will be tested with sputum culture. I understand that the testing with sputum culture may take 10 (ten) weeks[2].

f. I need to return for sputum collection on three consecutive mornings starting within seven (7) days of my chest X-ray. If I fail to return within seven days, I will forfeit the opportunity to obtain a TB Certificate.

g. If the smear or culture shows the presence of TB bacteria, I will be referred for TB treatment. Treatment shall be at my own expense; I will inform the TB treatment facility that I have close family contacts, who may need evaluation for TB.

h. I have the right to refuse to undergo the TB assessment procedure and TB treatment, but accept such a refusal may adversely impact on my UK visa application.

i. I understand that you have final the final decision about whether I receive a Certificate regardless of the clinical circumstances.

I hereby:

a. consent to undergo TB testing;
b. authorize you and your designated laboratory to store all relevant personal information collected during the assessment process, including health records and chest X-ray;
c. authorize you and your designated clinics to share my personal details and assessment results with the UK immigration authorities, the UK Department of Health, the UK Health Protection Agency and the UK National Health Service.
d. authorize you to share my assessment results with the health authorities of (name of the country) if the notification is required by the country's legislation.
e. I release and hold harmless the UK Government and you from any liability for loss, injury suffered or other harm during, or as a result of, the TB assessment procedures

I have read/had translated for me this consent form, I was invited to ask questions to clarify what was not clear to me. I understand the content of this declaration.

Applicant's signature ……Date……

Name (PRINT)……

[2] In a very small proportion of cases, where the sputum culture becomes contaminated, I understand that this process may take longer.

Important notes: (tick if applicable)

☐ Applicant has withdrawn consent (sign /date here)

Health professional ……..…….
Date ……..

☐ I refused the above assessment and understand that such refusal may negatively impact on my UK visa application.

Applicant's signature ……..
Name (PRINT) ……
Date ……

Witness's signature (if necessary)
A witness should sign below if the applicant is unable to sign but has indicated his or her consent.

Signature …… Date ……

Name (PRINT) ……..

Parental/legal guardian consent:

- I consent/do not consent to (NAME)…… undergoing the a TB assessment as described on this form.
- I confirm that I am the parent/legal guardian of this applicant.

Signature…….. Date……..

Name(PRINT)……

Relationship to applicant……

Name (PRINT)……

Statement of interpreter (where appropriate)

I have translated the content of this document for the applicant to the best of my ability and in a way in which I believe s/he can understand.

Signed ……..……..Date …….

Name(PRINT) ……..……

Health professional's declaration

I have explained to the applicant the TB assessment procedure, its purpose and possible risks, and have confirmed with the applicant that s/he has no further questions and wishes/does not wish the assessment to go ahead.

Signed:…….……..Date .. ……..

Name (PRINT) …….. ……

Guidance to health professionals

What a consent form is for:

This form documents the applicant's agreement, or otherwise, to go ahead with a TB assessment, performed in accordance with the UK protocol, for the purposes of his/her UK visa application.

NB: If applicants do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed.

Applicants are entitled to change their mind and withdraw their consent at any time after signing the form, up to completion of the TB assessment, as long as they retain capacity to do so.

This form may also be used to document consent to:

a) A child's assessment who (under the age of majority), where consent is given by the parent/legal guardian.

b) An adult's assessment, where the applicant does not have legal capacity to give consent, but has a legally appointed guardian to act on his/her behalf.

Who can give consent

Everyone over the age of majority or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated.

Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the granting of consent.

If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

A relative cannot be asked to sign this form on behalf of an adult who is not legally competent to consent for himself or herself, unless he or she has been legally appointed as the individual's legal guardian.

Information

Information should be given to applicants as to what the assessment will consist of, what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed.

Applicants should be told about 'significant risks which would affect the judgment of a reasonable patient'. 'Significant' has not been legally defined, but the UK General Medical Council requires doctors to tell patients about 'serious or frequently occurring' risks.

In addition if applicants make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare.

The applicant should be given the opportunity to ask questions and be given sufficient time to reflect on the answers given. You should always answer questions honestly.

Sometimes, applicants may make it clear that they do not want to have any information about the options, but want you to decide on their behalf which option should be taken. In such circumstances, you should not make a decision on their behalf.

Annex E:

UNITED KINGDOM PRE ENTRY TUBERCULOSIS SCREENING PROGRAMME

HEALTH QUESTIONAIRE FOR CHILDREN AGED UNDER 11

COMPLETE THIS FORM IN CAPITAL LETTERS

Your Child's Name.....……**Male ☐ Female ☐**

His/Her Date of Birth.....…/.....…/… **Nationality** ……

Passport number..... **Passport expiry date** .....…/.....…/..…

His/Her proposed UK address (if known)……

Postcode……. **Telephone No**…….....
If you/he/she is being sponsored to come to the UK:-
Type of sponsor (education/employer/family/other)…….....

Name of sponsor ……

Their address……...

Their postcode…….. **Telephone no** ……

Now answer all the following questions in respect of your child

1. Has anyone in the household in which he/she lives (including him/her and yourself) been diagnosed with TB (Tuberculosis) in the last 2 years?
Yes ☐ No ☐

2. At the moment, does he/she have a cough that has lasted for more than a month?
Yes ☐ No ☐

3. At the moment, is he/she coughing up blood (haemoptysis)?
Yes ☐ No ☐

4. Does he/she have a chronic respiratory disease such as cystic fibrosis or respiratory condition that limits activity or cyanosis (indicated by blue or purple coloration of the skin)?
Yes ☐ No ☐

5. Has he/she previously had thoracic surgery?
Yes ☐ No ☐

Information I provide to the Home Office will be treated in confidence but it may be disclosed to other law enforcement agencies, government departments including the UK Health Protection Agency and the UK National Health Service, UK local authorities, foreign governments and other bodies for immigration or research purposes or to enable them to perform their functions.

Your Signature..... **Today's date**...../...../.....

Annex F:

Ms/Mr. _____ DoB: _____,

Dear Applicant,

You have been screened for tuberculosis and you were found to have abnormal results.:

We would like to inform you that additional sputum culture tests, taken over three consecutive days, were positive.(Please see enclosed medical results).

I kindly requests you:

- ❑ Immediately show these results to your general practitioner (doctor or healthcare provider), who will arrange for tuberculosis treatment.

Thank you for your cooperation.

Yours truly,

Annex G:

Referral letter

Dear Colleague,

I refer to you

Ms/Mr. _____ DoB: _____, who underwent tuberculosis testing as a part of the UK visa application procedure and was found to have:

- ❑ X-ray signs of possible pulmonary tuberculosis:
- ❑ positive sputum smears
- ❑ positive sputum cultures

I kindly request you:

- ❑ monitor and investigate as appropriate
- ❑ undertake contact tracing as required
- ❑ initiate treatment as indicated

in accordance with the national policy and WHO guidelines.

We would appreciate it if, upon the completion of the treatment, you provided the patient with medical reports, reflecting the following information:

- For the patient: treatment regimen (drugs, doses, frequency, total number of doses, treatment period), complications, compliance, results of pertinent investigations, treatment outcome and recommendations.
- For the family contacts: period of follow up, pertinent investigations, chemoprophylaxis or treatment regimen (if applicable) and recommendations for further follow up.

Please note that these reports, though not obligatory for the visa application process, are very important for further follow up.

Thank you for your cooperation.

Yours truly,

Patient's declaration
Hereby I confirm that the results of tuberculosis detection process were provided to me, and the need for further management was explained to me, by the clinic. I was/was not handed a copy of my X ray and medical form which I was advised to present to the treating physician.

Signature: _____ Date: _____