

SECTION	Biological Safety
VI.	
Chapter 2	Tuberculosis Exposure Control Plan
Revision	3/2022
Date	

**TUBERCULOSIS EXPOSURE CONTROL PLAN**  
**(first approved July, 1995)**

***SCOPE: THIS PLAN APPLIES TO DUKE UNIVERSITY, DUKE HOSPITAL AND CLINICS, THE PRIVATE DIAGNOSTIC CLINICS, DUKE PRIMARY CARE AND DUKE ASSOCIATED PATIENT CARE AREAS. IN THIS DOCUMENT THESE ENTITIES WILL BE COLLECTIVELY REFERRED TO AS "DUKE".***

Preface

The primary purpose of this document is to detail a Tuberculosis Exposure Control Plan for Duke. This Plan was approved by the Hospital Infection Control Committee and Duke University Safety Committee in July 1995, with revisions approved June 1996, July 1997, July 1998, November 2000, December 2001, March 2003, February 2004, February 2005, February 2006, March 2007, March 2008, March 2009, February 2010, February 2011, February 2012, March 2013, February 2014, February 2015, February 2016, February 2017, March 2018, February 2019, April 2019, April 2021, September 2021, and March 2022.

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## I. INTRODUCTION

This plan incorporates the concerns and responsibilities of the numerous disciplines and departments involved with the control and management of tuberculosis (TB) among patients, students, employees, and visitors at Duke. This plan is designed to enhance and promote good patient care while simultaneously preventing the transmission of TB to other patients, students, employees, and visitors.

The very nature and essentials of patient care involve risk for the transmission of infectious diseases such as TB both to other patients and to health care workers. It is the goal of this plan to lower this risk as much as is reasonably possible using well established principles of epidemiology, biological safety, infection prevention, and patient care.

## II. OVERVIEW OF INFECTION PREVENTION MEASURES

This plan is based on a hierarchy of tuberculosis control measures based upon recommendations and guidelines published by the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), and applicable North Carolina State Administrative Codes. At the top of this hierarchical list of control measures are early detection, isolation and treatment of persons with active tuberculosis as well as engineering controls such as room ventilation designed to reduce the risk of exposure to persons with infectious tuberculosis by reducing the concentration of aerosols of infectious bacilli. The lowest stratum level on the hierarchy of tuberculosis control is personal protective equipment (PPE) such as a respirator. Such equipment is useful in situations of known or suspected high risk as an adjunct measure to engineering controls and physical separation of infected patients.

## III. RISK ASSESSMENT

A. Employee Occupational Health and Wellness (EOHW), the Biological Safety Division (Biological Safety) of the Occupational and Environmental Safety Office (OESO), and Infection Prevention will maintain records summarizing the results of all investigations of healthcare workers and patients with known exposure to *Mycobacterium tuberculosis* Complex (TB Complex).

B. **EOHW** will provide reports to the Hospital Infection Control Committee (HICC) quarterly that include, along with appropriate demographic information:

- 1) The number of hospital employees with known occupational exposure to TB,
- 2) The number of employees who had a TB assessment and their baseline status,
- 3) The number of employees who converted their TB status after a known exposure to a patient with active tuberculosis, and
- 4) The number of employees with exposure who were lost to follow-up.

C. **EOHW** will maintain records on all TB assessments done on new (baseline testing) and current employees (post-exposure TB testing). In an annual written report to Biological Safety for the TB Annual Report, EOHW will summarize, including appropriate demographic information, the following data:

- 1) Results of TB evaluations on new placements.
- 2) Results of TB evaluations on healthcare workers involved in known potential exposures.

D. **Biological Safety** will annually summarize and present the following to HICC and the Duke University Safety Committee (DUSC):

- 1) Duke hospital employee compliance to EOHW and OESO TB requirements,
- 2) The number of culture confirmed TB cases at Duke,
- 3) The number of employees investigated in potential TB exposure cases and the number of conversions associated.
  - a) Include any evidence of trends or unusual circumstances.
  - b) Include recommendations for preventing future potential exposures, if any.
- 4) The compliance rate of new healthcare worker TB evaluations
- 5) The total number of days of isolation for:
  - a) tuberculosis, and
  - b) suspected tuberculosis.

E. **Biological Safety** will assess the potential of occupational exposure to TB for all Duke healthcare workers. Since this encompasses multiple sites and types of services, specific areas or functional groups within the setting have separate risk classifications. Each employee will be assigned at least one of the following exposure determinations:

Airborne Pathogens:

- 0) No likely or anticipated exposure to TB Complex.

- 1) Work assignment for all or part of the employee's scheduled work time in areas where there is a low risk of exposure to TB aerosols (e.g., patient care areas/buildings)
- 2) Employee is an N95 respirator user (See Section VIII I).
- 3) Employee is a Powered Air-Purifying Respirator (PAPR) user (See Section VIII I).
- 4) High risk - Annual TB Screening. To be used for Clinical Microbiology Laboratory (CMB) employees working in acid-fast bacillus (AFB) section only.
- 5) Not in use
- 6) Not in use
- 7) Not in use
- 8) "Special EOHW Review" – annual TB Questionnaire with EOHW review for those employees with latent TB infection.

#### **IV. RESPONSIBILITIES**

##### **A. Employees**

- 1) All employees with exposure determinations of Airborne Pathogens 1 –4, and 8 are required to complete online educational programs related to tuberculosis control and comply with tuberculosis control policies outlined in this plan. Employees with a designation of Airborne Pathogens 2 or 3 must comply with the requirements of the Respiratory Protection Program Policy for TB (see Section VIII I).
- 2) Employees will conduct a "user seal-check" prior to each use of the N95 respirator.
- 3) Employees will report any incidents of possible exposure to tuberculosis to Infection Prevention, EOHW, or Biological Safety.
- 4) Employees flagged for N95 respirator use in high risk environments (Airborne Pathogens 2) must comply with all requirements, including the annual N95 respirator fit-test .

##### **B. Department Managers**

- 1) Document each of their employees' compliance with Duke's tuberculosis policies and compliance with OESO tuberculosis educational programs on their yearly performance evaluation.
- 2) Enforce the requirements of this plan.
- 3) Assist OESO/EOHW in the scheduling of any training, fit-testing, medical evaluations, or any other activity relating to compliance of this program.
- 4) Provide OESO with employee's job duties and physical location to help determine the risk
- 5) Assist OESO with collecting names of potential exposed employees during a TB exposure investigation.
- 6) Assure that appropriate respiratory protection is available.

**C. Hospital Infection Control Committee (HICC)**

- 1) The HICC receives reports annually from OESO and quarterly from EOHW that include any TB activity. Thereafter the HICC will report these findings to the Executive Committee of the Medical Staff.
- 2) The Chair of the HICC will review and then arbitrate any controversies or disagreements over proper isolation of individual patients with known or suspected tuberculosis. The authority for this activity is outlined in the bylaws of the Duke Hospital and Clinics Medical Staff. These bylaws specifically state the Chair of the HICC has the responsibility and authority to mandate specific isolation should disagreement occur between Duke Physicians and personnel from Infection Prevention and Hospital Epidemiology (IPHE).
- 3) The Chair of the HICC will be notified of any investigations of tuberculosis exposure of employees and students undertaken by Biological Safety and EOHW by report at HICC.
- 4) The HICC and the Duke University Safety Committee will review the Hospital TB Exposure Control Plan at least annually.

**D. Infection Prevention**

- 1) Assure compliance with Duke policies as to the initiation and discontinuation of Airborne Infection Isolation (All) of all patients with known or suspected infectious tuberculosis. See Section VIII

of this document, "Management of Patients with Known or Suspected Tuberculosis" for details on the specific safety precautions to be used with All. **On-call advice is available 24 hours a day, 7 days a week by calling Infection Prevention at 919-684-5457 or pager 919-970-9721.**

- 2) Participate (in conjunction with OESO and EOHW) in the orientation and continuing education of all new and current employees concerning tuberculosis control policies.
- 3) In conjunction with OESO and EOHW review the tuberculosis exposure control plan annually.
- 4) Report or assist in reporting all cases of known or suspected tuberculosis to the health department in the patient's county of residence. In turn, the health department will notify the NC Department of Health and Human Services (Appendix A).
- 5) Notify Biological Safety of all patients placed in isolation for confirmed infectious tuberculosis, all positive AFB smears in patients with suspected infectious tuberculosis, and all TB Complex positive specimens/cultures.

#### **E. Biological Safety/OESO**

- 1) OESO in conjunction with EOHW will assess the potential of each Duke employee for occupational exposure to TB. This assessment will include a review of each employee's work responsibilities with particular reference to their likelihood for occupational exposure to TB (see Section III E).
- 2) Educate all area supervisors of the requirement that this assessment be completed on all employees.
- 3) Collate, organize and provide data on exposure determinations and provide department managers and supervisors with access to reports regarding employee compliance to the requirements associated with their assigned exposure determination. Reports are also provided to EOHW, HICC, and the Duke University Safety Committee (DUSC) as needed.
- 4) Provide, document, and be responsible for any OSHA-required TB control training programs at Duke. All employees with exposure determination ratings of Airborne Pathogens<sup>1</sup> through 4, and 8 shall receive annual education concerning tuberculosis control.

Those employees with exposure determinations of Airborne Pathogens 2 or 3 will receive annual respirator training.

- 5) Assure that appropriate ventilation or other engineering controls required by this plan are provided as needed (i.e., monitoring monthly isolation room air pressure testing performed by Engineering & Operations (E&O) or other entity Engineering group).
- 6) Identify potentially exposed employees and students and provide this list to EOHW or Student Health, respectively, for further evaluation.
- 7) Manage and conduct annual reviews of the Respiratory Protection Program Policy for TB.
- 8) Provide on-call advice concerning the use and advisability of such units and for preparing and maintaining the “Portable HEPA Operating Instructions” sheet mentioned below.

**F. Employee Occupational Health and Wellness (EOHW)**

- 1) New Employee Screening – New employees who will receive a medical placement health review will receive TB screening as defined in Section V and will be evaluated for:
  - a) Prior TB history and any previous therapy for tuberculosis.
  - b) Prior TST or IGRA (Interferon Gamma Releasing Assay) results (to include dates of the most recent negative or positive results).
  - c) Prior therapy for active or latent tuberculosis including dates, types of treatment and results of prior chest radiographs.
- 1) Follow-up of all employees with potential exposures (see Section VI).
- 2) Follow-up and treatment of all employees with suspected tuberculosis (infection or disease):
  - a) CDC guidelines for the management of tuberculosis will be the basis for all therapeutic decisions after evaluation by an EOHW provider.
  - b) Evaluation of all employees with suspected or known active tuberculosis is the responsibility of EOHW. Such employees will be relieved from work until active disease is ruled out by



appropriate medical and microbiological studies. Grounds for removing any employee from work may include but are not limited to the development of signs or symptoms suggestive of active tuberculosis and/or radiographic changes consistent with active pulmonary tuberculosis. All employees with confirmed active tuberculosis will be reported to the health department in the employee's county of residence to facilitate evaluation of the employee's contacts outside Duke, especially children.

- 3) Follow-up of employees with non-occupational elevated risk for TB infection. These employees are identified through an annual questionnaire that is part of the annual online TB training.
- 4) Implement the Respiratory Protection Program Policy for TB (Section VIII.I).

#### **G. Duke Student Health Service**

- 1) All incoming Duke Students will be screened through a TB Screening Questionnaire. Students identified as high risk will be required to submit a TST or IGRA within 6 months prior to matriculation.
- 2) All Duke medical students and other allied health students will have tuberculosis testing within 6 months prior to matriculation.
- 3) Duke Student Health only performs IGRA blood tests and no longer places PPDs.
- 4) Students with a history of a positive TB test will be required to submit a symptom monitoring checklist, a chest x-ray done in the US in the last 2 years, and a TB Clearance Statement signed by a provider, if indicated. If the student provides documentation of treatment for active or latent TB, no chest x-ray is required.
- 5) All students who have a documented or suspected exposure to a patient with infectious tuberculosis will be evaluated at the Student Health Center using the same criteria as for Duke Employees (see Section VI).
- 6) Students have 7 days following notification of the need for post-exposure tuberculin testing in which to record a current tuberculin test result with Duke Student Health. Any student who has not had tuberculin testing results recorded in Student Health within two weeks of the notification will be restricted from clinical rotations by

their respective Health Science Program. A second test will be required approximately 8 – 10 weeks after exposure.

- 7) Students who perform patient care activities and travel to countries or areas within the U.S. designated by CDC/WHO as high hazard/high burden for TB must have a recorded tuberculin test result with Duke Student Health within a time frame of greater than 8 – 10 weeks and not more than six months after returning to Durham. Noncompliant students will be restricted from clinical rotations by their respective Health Science Program.
- 8) Any student with active tuberculosis will be restricted from the classroom/patient care/campus study and living areas until treated and evaluated by the same criteria used to manage Duke employees.

#### **H. The Clinical Microbiology Laboratory (CMB)**

- 1) Specimens will be accepted for TB Complex isolation, identification, and susceptibility testing in the CMB Laboratory, Room 0170, Wadsworth Bldg.. Routine AFB smears and cultures will be done during weekdays. Sputum samples with positive AFB smears will have MTBC-PCR reflex testing performed. The CMB Laboratory will report all positive TB Complex test results to Infection Prevention and forward these results to the NC Department of Health and Human Services electronically.
- 2) Due to differences in transmissibility, isolates of the TB Complex will be identified when disease is suspected to be caused by a member of the TB Complex that is not *Mycobacterium tuberculosis*. Requests for speciation can be made by Infectious Disease, Infection Prevention, Biological Safety, or a physician involved with the case.
- 3) CMB will provide an annual report to Biological Safety summarizing all isolates of TB Complex and their susceptibilities.
- 4) **Positive Smear Results and Positive Identification of TB Complex**

CMB will call the patient's physician and Infection Prevention (919-684-5457 or 919-970-9721) with:

- a) The first positive AFB smear result of each admission or encounter;

- b) The first positive identification of TB Complex (e.g., *Mycobacterium tuberculosis*, *Mycobacterium bovis*, or *Mycobacterium africanum*) per patient;
- c) Susceptibility results on drug-resistant isolates; or
- d) A noted change in the susceptibility pattern of the patient's most recent isolate.

#### **I. Anatomic Pathology**

- 1) The Department of Pathology (including Autopsy, Cytopathology and Surgical Pathology) will notify Infection Prevention and the patient's provider when specimens, tissues or organs are found on pathological examination to exhibit findings consistent with an infectious form of tuberculosis. These reports will be made by phone and in writing to Infection Prevention. Whenever possible samples of these suspicious specimens will be sent to the Clinical Microbiology Laboratory for AFB culture to confirm disease and for epidemiological investigations by Biological Safety and the North Carolina public health system.
- 2) The Autopsy Service will notify Infection Prevention when thick-walled cavitory lesions of the lung containing caseous necrosis are found to communicate with an open bronchus or when a granulomatous laryngeal lesion of unknown etiology is encountered.
- 3) The Pathology Department will notify Infection Prevention when microscopic examination of any surgical or autopsy specimen discloses any form of tuberculosis.
- 4) The Surgical Pathology Department will notify Infection Prevention when they encounter any necrotizing caseous granulomatous lesion with or without a cavitory component which has findings consistent with an infectious form of tuberculosis. All procedures that have the potential of producing aerosols on specimens from patients known to have active multi-drug resistant tuberculosis are to be performed within a certified biological safety cabinet using appropriate biosafety precautions for the specific process/procedure in accordance with CDC/NIH guidelines.
- 5) The Cytopathology Unit will notify Infection Prevention of any AFB smear-positive results.

#### **V. TUBERCULOSIS SCREENING**

A. Tuberculosis screening is required for new employees working in patient care areas or buildings including new unpaid workers (e.g., volunteers, providers, and observers). Student Health performs TB testing on Duke Health Science students if indicated. TB testing is also required of all students volunteering for the first time in the Health System and those newly matriculated students identified as high risk per the TB Screening Questionnaire. Additionally, all healthcare contract workers must comply with Duke Policy through their respective agencies prior to job placement.

B. EOHW will provide annual summaries of tuberculosis screening with documentation of any TB conversions to Biological Safety/OESO.

C. TB testing will be performed on all new employees working in patient care areas or buildings unless they have one of the following conditions:

- 1) Documentation of a prior TST reaction interpreted as positive according to CDC guidelines (see section F) or positive IGRA (interferon gamma release assay). The employee must provide documentation of a previous positive test or the employee will be tested again by EOHW.
- 2) Documentation of prior treatment for tuberculosis infection or disease.
- 3) Documented as currently receiving anti-tuberculosis therapy.
- 4) Documented negative test within the last year.
- 5) Employees with documentation of allergy (i.e., immediate hypersensitivity) to TST reagents will receive an IGRA in lieu of a TST.

D. A questionnaire will be included as part of the annual TB training that will help identify healthcare workers who are at increased risk of TB infection due to non-occupational activities. These employees that are identified will be given a TB evaluation by EOHW.

E. Employees will be asked at the time of testing whether they have known or suspected immunosuppressive conditions (e.g., HIV infection, prior organ transplantation or recent or current chemotherapy); such individuals will be evaluated and counseled by an EOHW provider regarding their risk of TB.

F. A standard TST will employ 0.1 mL (5 units) of tuberculin and will be read 48-72 hours after placement by personnel from EOHW whenever there is any reaction of redness or induration. A TST without redness or induration may be read by other licensed HCWs (i.e., MD, RN, PA, or NP). Student Health will read all TSTs for students.

1) Two step TST will be done on individuals in the following groups (unless employee provides documented 2 step TST or IGRA within the previous twelve months).

- 55 years of age or older
- Coming from an area with a high prevalence of TB [according to current data from the World Health Organization](#) (WHO) with a documented prior negative TST.
- A history of BCG with a documented prior negative TST.
- Equivocal prior test results.

2) An IGRA will be done on individuals in the following groups (unless employee provides documented 2 step TST or IGRA within the previous twelve months):

- Coming from an area with a high prevalence of TB according to current data from the WHO, without a documented prior negative TST.
- A history of BCG, without a documented negative TST.

G. All TST reactions meeting the following criteria will be classified as positive:

- **Greater than or equal to 5 mm of induration if:**
  - a) The employee is a close recent contact of a patient with infectious tuberculosis.
  - b) Their screening X-ray shows fibrotic changes thought to be consistent with old, healed tuberculosis infection.
  - c) The employee has known or suspected HIV infection.
  - d) Individuals with organ transplants and other immunosuppressed patients, including those receiving >15 mg per day of Prednisone for a month or longer or persons taking or considering taking tumor necrosis factor (TNF) inhibitors such as etanercept (Enbrel®), infliximab

(Remicase®), adalimumab (Humira®) or anakinra (Kineret™).

- **Greater than or equal to 10 mm induration** if one or more of the following are present:
  - a) Other medical risk factors known to substantially increase the risk of tuberculosis disease once infection has occurred (see Section VIII A).
  - b) Foreign-born person from a country with an elevated TB rate. Includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe.
  - c) The employee has had recent residence in a high prevalence area for tuberculosis.
  - d) Recent IV drug abuse has occurred or is suspected.
  - e) The employee has regular employment in a patient area or other high hazard area.
- **Greater than or equal to 15 mm induration** if the employee is not in one of the two categories mentioned above.

H. Employees with positive tuberculosis testing:

- 1) Personnel with LTBI (latent TB infection) are required to complete an annual questionnaire that includes specific questions concerning the absence or presence of symptoms suggestive of active tuberculosis or other risk conditions (see Section VIII A).
- 2) Employees who have LTBI and who have completed a course of preventive therapy in accordance with CDC recommendations also require an annual questionnaire assessing symptoms suggestive of active TB.
- 3) Employees who are new converters:
  - 1) All employees with documented recent TST or IGRA conversion will be counseled by EOHW and have the following tests:
    - a) Chest x-ray.

- b) Clinical assessment that includes evaluation of the patient's health history, including high risk associated disease(s) (see Section VIII A), possible source of conversion and whether the conversion was likely or possibly related to their occupation.
    - c) HIV testing.
  - 4) Preventive therapy will be recommended for all recent tuberculin or IGRA converters consistent with current recommendations of the CDC/USPHS and the Tuberculosis Advisory Group.
  - 5) If no drug prophylaxis is given for LTBI and conversion is within two years, a chest x-ray is repeated after 18-24 months.
- I. Treatment of employees with active tuberculosis:
  - 1) Anti-tuberculous therapy based on current CDC recommendations will be advised for all employees with active tuberculosis. Treatment is with the employee's personal physician or with the health department in the employee's county of residence. Employees will be relieved from work activities until EOHW authorizes their return. The local health department will be notified and consulted.
  - 2) All employees with active tuberculosis will be informed of the risk of disease among household contacts. In such instances, follow-up and treatment of household contacts will be the responsibility of the local health department.
- J. Pregnancy is not a contraindication for tuberculin skin testing. The same guidelines used for non-pregnant employees will be utilized to test and evaluate pregnant employees with two exceptions:
  - 1) Pregnant employees infected with TB Complex will be informed of the possibility that infection can progress more rapidly during pregnancy.
  - 2) Pregnant employees who meet current guidelines for prophylactic therapy or treatment of active disease will be handled on an individual basis in conjunction with their primary physician. [Note: both INH and Rifampin are considered safe for use in pregnancy in general, preventative therapy and treatment of active disease are considered safe and appropriate in pregnant women].

## **VI. EXPOSURE INVESTIGATION**

An exposure will be defined as spending time in an enclosed space with a patient with smear positive, pulmonary, infectious tuberculosis where adequate All precautions were not utilized. Smear status to determine infectiousness is smear results collected on three respiratory specimens prior to initiation of anti-tuberculosis medication treatment. Consultation with the Health Department TB Nurse in the patient's county of residence to determine the scope of the investigation will be pursued as needed. Exposure to TB aerosols (both smear negative and positive) during certain procedures (e.g., bronchoscopy, laboratory accidents, irrigation of surgical sites or wounds, extubation, suctioning, frozen sections, HVAC repair, etc.) is also an exposure.

- A. Infection Prevention will notify OESO when a patient with infectious tuberculosis has been admitted to the hospital or seen in the clinics. It will be the responsibility of EOHW and OESO to follow up on possible employee exposures.
- B. Records of patients will be reviewed to collect names of potentially exposed employees and estimate cumulative potential exposure time for these employees. OESO will notify Department Managers of all such exposures; Infection Prevention will notify the physicians of exposed patients. It will be the joint responsibility of OESO and Department Managers to prepare a list of exposed employees for subsequent follow-up and evaluation. It will be the responsibility of individual physicians to notify exposed patients and arrange for their follow-up and evaluation.
- C. Post-exposure testing using the concentric circles method, will focus on staff that constitute a "first circle" of exposure such that the maximum number of staff tested in most cases will be less than 20. Any conversions within this first group will result in testing of all those exposed. In addition, community conversion data on all cases will be aggressively pursued to assist with the decision on the depth of testing. Exposed staff will be asked to define their estimated cumulative hours of exposure, if needed. All such evaluations will include the documentation of the circumstances of the exposure, the level and duration of the exposure, and the presence or absence of signs and/or symptoms of active tuberculosis in the source patient. Those chosen for "first circle" testing will be those with the most exposure time.
- D. Surgical Pathology/Autopsy employees who are directly involved with the handling and/or preparation of surgical specimens confirmed as positive for TB complex will be included in TB exposure investigations when All precautions were not utilized.
- E. Employees to be evaluated will be notified and evaluated by EOHW. All such evaluations will include the presence or absence of signs and/or symptoms of active tuberculosis in the exposed employee, prior TB status of the employee and the subsequent risk of tuberculosis infection and/or disease in the



employee. Once notified, it is expected that the employee will have tuberculosis testing. Employees have 7 days post notification to respond or their department director or chairperson will be notified. Any employee who has not had tuberculosis testing results recorded in EOHW within two weeks of the notification will be restricted from further work at Duke.

- F. In addition, OESO or EOHW will notify outside contractors if any of their employees have been exposed to tuberculosis. It will be the responsibility of these outside contractors to contact such exposed individuals and arrange for their appropriate evaluation and follow-up.
- G. Exposed employees will have their TB status established following a significant exposure. If the employee has not had a TST placed within the last three months prior to the exposure, a baseline TST will be placed at that time. When such tests are negative, a follow-up TST will be repeated 8-10 weeks post-exposure. If employee has a history of BCG or life in an area endemic for TB then IGRA can be used for testing.
- H. In all instances of nosocomial transmission of tuberculosis an attempt will be made to identify the source. When a source patient is identified, drug susceptibility testing will be performed and the results of these studies will be shared with all physicians who evaluate and treat exposed or infected contacts.
- I. When an employee returns from providing patient care in a country that has a high prevalence of TB according to current data from the [World Health Organization](#) the employee will undergo evaluation by EOHW when returning to work at Duke.

## **VII. EDUCATION**

- A. Responsibility for education of staff concerning tuberculosis control policies, procedures and their implementation will be the responsibility of OESO.
- B. All Duke medical students and allied health students will receive instruction on TB control measures from OESO before rotations in patient care or CMB.
- C. All employees whose jobs involve a potential for exposure to tuberculosis will receive education that is specific for their work responsibilities. Such training is conducted at the time of employment by OESO and annually thereafter. Although the level and detail of this training may vary according to job description, the following elements are included in orientation training for employees with exposure determination ratings of Airborne Pathogens 1- 3, and 8:

- 1) Basic concepts of the transmission, pathogenesis and diagnosis of tuberculosis (including the difference between tuberculosis infection and active disease due to tuberculosis, potential signs and symptoms of tuberculosis and the possibility of late reactivation of asymptomatic tuberculosis infection).
- 2) The risk of occupational exposure to tuberculosis, the rationale for isolation and situations that increase the risk of exposure to tuberculosis, and the steps to be taken if exposure occurs.
- 3) The hierarchy of control measures designed to prevent transmission of tuberculosis outlined in this plan and a summary of policies and procedures related to this goal. Area-specific control measures will be provided to personnel who work in areas with special or unique risks.
- 4) A questionnaire will be included as part of the annual TB training that will help identify healthcare workers who are at increased risk of TB infection due to non-occupational activities. These employees that are identified will be given a TB evaluation by EOHW.

D. All records related to education and training of employees will be stored in a computer database maintained by OESO. Statistical summaries of TB training compliance will be provided at least annually to the HICC and the DUSC by OESO.

## **VIII. MANAGEMENT OF PATIENTS WITH KNOWN OR SUSPECTED TUBERCULOSIS (TB)**

### **A. Recognition and Initial Diagnosis of Patients with Potential TB Disease**

#### **1. Signs and Symptoms of Active Pulmonary TB:**

- Persistent cough (> 3 weeks)
- Hemoptysis (bloody sputum)
- Fever
- Night Sweats
- Unexplained weight loss
- Chest X-ray changes suggestive of TB
- Chest pain
- Anorexia
- Fatigue

#### **2. Groups at High Risk for TB:**

- Close contacts of active TB cases
  - Individuals born in countries with high TB rates (refer to [the World Health Organization's website](#) for updated information).
  - Alcoholics / IV drug abusers
  - Residents and employees of high-risk congregate settings (e.g., long-term care facilities, homeless shelters, or prisons)
  - Persons with certain medical conditions that increase the risk of developing clinical tuberculosis once tuberculosis infection has occurred:
    - HIV infection (due to immunosuppression)
    - Silicosis
    - Abnormal chest radiograph showing fibrotic lesions
    - Diabetes mellitus
    - Prolonged corticosteroid therapy
    - Immunosuppressive therapy
    - Hematologic and reticula endothelial diseases
    - End-stage renal disease
    - Intestinal bypass
    - Post-gastrectomy
    - Chronic malabsorption syndromes
    - Head, neck, and lung cancers
    - Being 10% or more below the ideal body weight
3. **Diagnosis of TB** should be considered in any patient presenting with signs and symptoms of active TB. Also, if a patient presents with only one or two of these signs and symptoms and belongs to one or more of the groups at high risk for TB, then suspicion for active TB should be raised.
- **Place the patient on All immediately**; details follow (see VIII.D below).
  - Appropriate diagnostic studies should be conducted. These may include:
    - TST or IGRA
    - Three consecutive sputum specimens collected at least eight hours apart, one of which should be an early morning specimen. These sputum specimens are used to perform smears and cultures. The three smear results are used to determine infectiousness.
    - In smear positive sputum specimens a polymerase chain reaction (PCR) test should also be performed. A positive PCR test is confirmatory for TB complex. For inpatient testing, a negative PCR test should be

repeated once on a second smear positive sputum specimen.

- Chest radiography. In patients with normal immune systems the chest x-ray is often the most valuable tool used to raise suspicion for TB. Persons with impaired immune systems often do not have chest x-rays suggestive of TB even though they may have the disease.
  - In selected instances, bronchoscopy, sputum induction by nebulizer, nasogastric aspirations (for pediatric patients), and/or bone marrow biopsy may be undertaken.
  - All initial specimens from any source should have AFB cultures performed.
  - Drug susceptibility testing should be performed on all initial TB complex isolates.
4. When patients with previously diagnosed pulmonary or laryngeal TB, who remain on treatment, are admitted to or seen at Duke, All must be utilized pending further assessment and evaluation of their infectiousness. Questions concerning prior TB treatment should be directed to the TB clinic at the patient's county health department. On weekends, holidays, or after hours when the health departments are closed, place the patient on All and contact the Infection Prevention nurse on call (919-970-9721).
  5. All is required for patients with respiratory smears positive for AFB in whom an alternate diagnosis has not been established or strongly expected and PCR results are not available.
  6. All is required for any patient with active multi-drug resistant TB (MDR-TB). Isolation may not be discontinued without approval from an Infectious Disease physician and Infection Prevention.
  7. All is required for patients with known or suspected TB abscesses/wounds that are open/draining, have drains in place, or are undergoing dressing changes until two weeks of appropriate therapy has been completed AND approval from Infection Prevention has been obtained.
  8. **For pediatric patients** placed on All for known or suspect TB, their primary caregivers must be suspected as the source of the patient's infection until they are proven to be free of TB disease. Follow the Infection Prevention Policy, "Inpatient Management and Screening for Caregivers of Pediatric Patients with Known or Suspected Tuberculosis", found on the Duke Intranet.

## B. Discontinuation of All

1. Three sputum smears, collected prior to the initiation of anti-tuberculosis medication therapy, and collected at least eight hours apart, of which one is an early morning specimen, are all negative.
  - Failed attempts to collect sputum specimens, with nursing supervision and documentation, will be followed by three attempts to collect induced sputum by nebulizer. If these attempts fail, and are documented, then All can be discontinued.
  - A smear negative BAL specimen counts as one negative AFB smear. Two additional negative smear results (or negative attempts at sputum induction) are required to discontinue All.
2. PCR testing is negative on two sputum smear positive specimens.
3. An alternate diagnosis or explanation of symptoms exists and is documented by the attending physician in the patient's medical record.
4. An evaluation by an Infectious Disease physician has deemed TB unlikely. Patients have negative smears as described above and the suspicion for TB is not high. Patients on empiric TB therapy are to remain in isolation despite negative sputa until other criteria for discontinuation of TB therapy are met.
5. Patients with confirmed, active pulmonary or laryngeal TB who require continued hospitalization shall be kept on All until they are no longer infectious, defined as:
  - They have been compliant on tuberculosis medications to which the organism is judged to be susceptible for at least 14 days;  
AND
  - There is evidence of clinical response to tuberculosis treatment;  
AND
  - Three consecutive sputum smears collected at least eight hours apart are negative. For patients with initial smear-positive disease, these specimens should not be collected until after at

least 14 days of treatment and 7 days from the last positive smear.

- Failed attempts to collect sputum specimens, with nursing supervision and documentation, should be followed by three attempts to collect induced sputum by nebulizer. If these attempts fail, and are documented, and all other criteria are met, then All can be discontinued.
6. For wounds or open draining lesions that are culture positive for TB complex, All can be discontinued after the patient is on effective anti-tuberculosis treatment for two weeks AND approval from Infection Prevention has been obtained.
  7. Under special circumstances, All may be discontinued at the discretion of Infection Prevention in collaboration with the IP Medical Director.

### **C. Discharge Planning Criteria**

1. Unless discharged to an institution with All rooms or home (with the restrictions as required by the health department in the patient's county of residence), discharge of patients with active TB requires meeting the criteria above for discontinuing All (see Section VIII.B).
2. Contact the health department in the patient's county of residence no less than 48 business hours before a patient with active TB is discharged. The PHE or Infection Prevention will provide assistance to the Case Manager, as needed, in contacting the patient's local health department ensuring that the health department is provided with the specific information required prior to discharge.
3. Patients should not be discharged to home while considered infectious if there are persons in the household who are at high risk of acquiring active TB (such as children less than five years of age, persons infected with HIV, or others who are severely immunocompromised).
4. It is the responsibility of the attending physician to write discharge orders that adhere to provisions described above. These criteria can only be altered at the discretion of the Chairman of the HICC in corroboration with the patient's personal physician and/or the local health department.

## D. Inpatient All Precautions

1. All may be initiated by attending physicians, consulting physicians, triage nurses, inpatient nurses, physician assistants, nurse practitioners, the PHE, or Infection Prevention personnel. Orders initiated by a healthcare provider other than a physician are valid for 24 hours, during which time a physician must co-sign the orders or write an order to discontinue All.
2. Patients with known or suspected infectious TB will be housed in a designated All room (Appendix D) with the wearing of approved protective respiratory devices by all persons entering the patient's room. Approved respiratory devices are described in detail in VIII I, and include N95 respirators for those who are fit-tested and PAPRs for those who are not fit-tested and not working inside a sterile field. See Section VIII I for instructions on ordering PAPRs from Equipment Distribution.
3. Bacterial/viral filters will be used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
4. Patients placed on All will be instructed by their medical and nursing staff on the need to adhere to All policies and to cover their mouth and nose with tissues when coughing and sneezing.
5. **Visitors** of patients in Airborne Isolation for suspected or confirmed pulmonary TB should be limited to immediate adult household members. Visitors are to wear the posted PPE, including N95 respirators, while in the patient's room. The patient's primary nurse is responsible for providing the visitors with instructions on how to wear the N95 respirators and how to perform a user seal-check (see appendix G) before allowing the visitors to enter the patient's room.
6. If a designated All room is not available (i.e., all are being used for All), or if it would not be medically appropriate to place the patient on one of the designated units (i.e., an obstetric or pediatric patient) then the patient will be placed in the back-up All room for the area they are in (Appendix D lists the designated and back-up All rooms). Designated All rooms and back-up All rooms have negative airflow capability and dedicated exhaust.
7. If an All room (designated or back-up) is not available or if the patient is in an area that lacks All rooms (e.g., Radiology) then a portable high-efficiency particulate air (HEPA) filter will be placed in the patient room (refer to Section VIII.G.2). The portable HEPA

should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing, follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). For areas that do not have their own portable HEPAs, one can be ordered from Equipment Distribution through the Service Now Portal. ***(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).*** Infection Prevention should be notified of this room decision when housing patients.

8. **Patients** are to stay in their All rooms until infectious TB has been ruled out. The only time a patient may leave their room is if a necessary procedure must be performed outside of the All room. Patients who refuse to adhere to All policies will be reported to the Durham County Health Department. Legal action may be taken to enforce appropriate All precautions when requested by the attending physician, the PHE, or Infection Prevention. The Duke Police will assist local law enforcement as needed in enforcing court-ordered isolation.
9. In the event that a patient with known or suspected TB must be transported to another area within the hospital for any reason, the patient must wear a surgical mask that covers the nose and mouth during the period of transport. Persons who transport such patients do not need to wear respiratory protection outside the All room while the patient is wearing a mask. In instances where diagnostic testing must be done outside the All room, efforts to schedule the procedure at a time when it can be performed rapidly and without prolonged waiting are encouraged. In such instances, the receiving area will be notified that the patient requires All.

#### **E. Outpatient All Precautions (Refer to Appendix B for Clinic Flowchart)**

1. Before a known TB patient arrives confirm that the patient is no longer infectious (by contacting the health department in the patient's county of residence) or reschedule the visit if medically possible. If a known infectious patient must come to the clinic then the patient should be instructed to wear a surgical mask (or have wounds covered) when entering the building where the clinic is located - and clinic staff should place the patient directly into the exam or procedure room and close the door – the patient should not spend any time in a waiting room with other patients or visitors. These precautions should also be taken with coughing children with known or suspected tuberculosis. For pulmonary disease, if the



patient can wear a surgical mask during their entire visit employees do not need to take respiratory precautions.

2. If the suspicion of infectious TB disease is discovered during a clinic visit, place a surgical mask on the patient as soon as possible and close the exam door. Contact the health department in the patient's county of residence and make plans to refer the patient (after hours contact a local Emergency Department, if medically indicated). Keep the patient in an exam room with the door closed until the patient can be referred. Ventilation time for exam rooms if the patient cannot wear a surgical mask is one hour with the door closed. In a medical emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not (and employee performs and passes user seal check).
3. To discontinue All precautions for a patient that is in the clinic the criteria described above in VIII. B. and C. must be met with the exception that only one PCR test is performed on one smear positive sputum specimen for outpatients.
4. Before discontinuing All precautions for subsequent clinic visits by the patient, clinic personnel should obtain verification that the patient is receiving effective therapy and is no longer infectious by contacting the health department in the patient's county of residence.
5. In Duke Clinic, if the patient cannot wear a surgical mask for the entire visit:
  - a) If an All room is not available, a portable HEPA should be placed in the exam or procedure room where the patient will be seen (refer to Section VIII G 2). The portable HEPA should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). If a clinic does not have a portable HEPA unit assigned to it, one can be ordered through the Service Now Portal. **(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).**
  - b) All employees entering the room or enclosed area where there is a patient who is not wearing a surgical mask and has known or suspected tuberculosis must wear an appropriate respiratory protection device. Proper protective respiratory devices are described in detail in Section VIII.I and include N95 respirators

for those employees who are fit-tested and PAPRs for those who are not fit-tested. If PAPRs are needed in an area where they are not stocked or if additional PAPRs are needed they can be obtained through the Service Now Portal. ***(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).*** The disposable head coverings are ordered from Material Services. In unanticipated events with an unmasked patient a N95 respirator is appropriate temporary protection whether the employee is fit-tested or not (and employee performs and passes user seal check).

#### **F. Emergency Medical Service:**

1. For patients with known or suspected tuberculosis, the vehicle's ventilation system should be operated in the non-recirculating mode, and the maximum amount of outdoor air should be provided to facilitate dilution. Use the rear exhaust fan if one is present.
2. If the patient is on All the drivers and other employees present in the enclosed vehicle with the patient must wear appropriate respiratory protection (see Section VIII.I).
3. If the patient has signs or symptoms of infectious TB disease consider having the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.

#### **G. Engineering Controls**

##### **1) All Rooms – Inpatient (Refer to Appendix D for All Room Instructions)**

Patients with known or suspected tuberculosis will be placed in All rooms following the criteria described in Appendix D. The doors for these All rooms must remain closed, and entrance is allowed only through anteroom doors. Allow 30 minutes after a known or rule out tuberculosis patient leaves an All room before entering without respiratory protection. During this time the doors should remain closed as much as possible. Such designated All rooms remain under negative air pressure with respect to the corridor, have a minimum of six air exchanges per hour (12 air exchanges per hour for new construction) and have appropriate exhaust capabilities, (i.e., dedicated outside exhaust or exhaust through HEPA filtration). Negative pressure is tested daily when a patient is on All precautions by the care nurse using the tissue test and documented on the "Negative Air Pressure Test Log" (see

Appendix E). This log is maintained on each nursing unit, procedure area, or clinic. Monthly air pressure testing by manometer is performed by E&O. This record is maintained by OESO. In addition, a list of All rooms (See Appendix C) will be maintained by OESO and provided to Bed Control, departmental managers, nurse managers, the PHE, and Infection Prevention. It is the responsibility of OESO to maintain records on the monthly testing and utilization of these isolation rooms and to notify the HICC of deficiencies and inadequacies of ventilation controls.

## 2) Portable High-Efficiency Particulate Air Filter Units

On-site hospital and clinics, and at any off-site clinics that have them, portable high-efficiency particulate air (HEPA) filter units will be used in the control of tuberculosis in known or suspected cases of infectious tuberculosis **in any area where such patients may be roomed and recommended All ventilation is not available. Infection Prevention will be notified of such situations.** The portable HEPA should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). OESO will be responsible for education concerning the proper utilization and maintenance of such devices. Portable HEPAs are available from Equipment Distribution through the Service Now Portal. **(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).** OESO has the responsibility for providing on-call advice concerning the use and advisability of such units and for preparing and maintaining the “Portable HEPA Operating Instructions” sheet mentioned above. Clinical Engineering is responsible for the electrical safety and motor performance of the units. The biological safety cabinet certification contractor for the university and health system (on contract through Duke University Procurement Services) provides annual certification and service which includes monitoring and changing the filters as necessary.

## H. High Hazard Procedures:

- 1) Cough-inducing procedures (e.g., bronchoscopy, sputum collection, sputum induction, aerosolized pentamidine treatment, etc.) on patients with known or suspected tuberculosis should be performed
  - a) In rooms that meet the ventilation requirements as outlined for All rooms (Section VIII.G.1 and Appendix D).
  - b) If such rooms are not available, supplemental control devices such as isolation booths or portable HEPAs must be

employed (refer to Section VIII.G.2 for information on portable HEPA's). Portable HEPA's should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)).

c) After completion of cough-inducing procedures, patients with known or suspected tuberculosis must remain in the isolation booth or All room until coughing subsides and be instructed to use tissues to cover their mouth and nose when coughing.

d) Cough-inducing procedures other than inductions to collect sputum samples for TB evaluation should not be performed on patients with active tuberculosis unless absolutely necessary.

e) Employees must wear respiratory protection while cough-inducing procedures are performed on patients with known or suspected tuberculosis (see Section VIII.I).

f) Patients with known or suspected tuberculosis who are recovering from sedatives or anesthesia following procedures such as bronchoscopy must be monitored in a separate All room or be recovered in the procedure All room.

g) After the patient leaves the treatment or procedure room, the room should remain closed for 30 minutes. Any staff members needing to enter the room during this time period will need to wear appropriate PPE and a HEPA filter should be left running. .

## 2) Aerosol-Generating Procedures:

a) Autopsy rooms should meet the criteria for All rooms in Section VIII.G.1. They must be at negative pressure with respect to adjacent areas and the room air should be exhausted directly to the outside of the building because infectious aerosols are likely to be present. Respiratory protection must be worn by personnel [and a portable HEPA unit must be running](#) while performing autopsies on deceased persons who may have had TB at the time of death (see Section VIII.I).

b) Laboratory workers handling specimens potentially containing TB organisms must adhere to the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL). For example, procedures causing aerosolization of TB must be performed within a Biological Safety cabinet (BSC) in a BSL-3 laboratory. Laboratories without BSCs should be evaluated by Biological Safety for alternative control measures.

## I. Respiratory Protection Program Policy

- 1) All employees must wear an appropriate respiratory protection device to enter an enclosed area with a known or suspected active pulmonary tuberculosis patient is located.
- 2) Appropriate respiratory protection is worn by all personnel performing or assisting in cough inducing procedures such as bronchoscopy or the delivery of aerosolized pentamidine treatments on patients with known or suspected TB.
- 3) Appropriate respiratory protection must also be worn by personnel mixing or administering BCG outside of a Biological Safety cabinet.
- 4) Appropriate respiratory protection is worn by all personnel performing or exposed to TB aerosol-generating procedures in the autopsy suite or in the clinical laboratory and those Engineering and Operations HVAC employees who may be exposed to TB aerosols in the air handling system.
- 5) The Respiratory Protection Program for TB is administered by OESO, EOHW and Student Health.

Background: The “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities” were first published by the CDC in October 1994. These recommendations, specified that respiratory protection be provided for employees that have the potential to be exposed to TB aerosols. Duke’s *TB Exposure Control Plan* was developed in response to this CDC guideline. Beginning January 1, 2005 the use of respirators for protection against TB Complex is regulated by [OSHA Standard 29 CFR 1910.134](#). In accordance with this OSHA requirement, Duke modified the [Duke Respiratory Protection Policy](#) to include TB and developed the [Respiratory Protection Policy for TB, SARS, and Other Airborne Particulates in Clinical Settings](#). Then, in December 2005, the CDC published an updated version of their guidelines titled “[Guidelines for Preventing the Transmission of \*Mycobacterium tuberculosis\* in Health-Care Settings, 2005](#)” and these updates have been incorporated into this document. Duke requires all employees, students, etc., who have the potential to be exposed to TB aerosols to participate in the Duke Respiratory Protection Program. This program is managed through OESO. All individuals included in the program receive medical clearance, training on respirator usage, and fit-testing to select an appropriately fitting respirator.

In order to minimize the number of persons who must be entered into the Respiratory Protection Program, every effort will be made to cluster patients on All onto the designated TB nursing units

(2100, 2300, 4300, 5100, 7800, 8100, 8300, 9300, 6 East, 6 West, and 7 East). Personnel included in the program will include, but are not limited to, personnel listed in Appendix E that may have direct contact with a patient on All or the potential to be exposed to TB aerosols generated during high hazard procedures.

- 6) The N95 respirator (N95):
  - a) A list of personnel requiring N95 respirator fit-testing can be found in Appendix E. Employee fit-testing for airborne pathogens is performed by OESO/EOHW or other staff trained by OESO. Students needing respiratory protection are fitted by Student Health.
    - a. The primary respiratory protection device is the N95. Every effort will be made to qualify all employees covered under the respiratory protection program with the N95. It is important to note that these respirators are authorized for use in protecting employees from TB droplet nuclei.
  - b) Training on the proper use of N95s is required.. On-line training is available at [OESO's Safety Training Website](#). The module is called "Respirator Training for Airborne Pathogens".
  - c) The N95 will be available at all rooms or areas housing patients requiring All. The N95 respirator mask is approved for individual use only and cannot be shared between medical personnel working in the same area at different times. The same mask cannot be used by employees caring for different patients. It can be reused with the same patient as long as: 1) it is properly stored, 2) it is not visibly contaminated, and 3) it is intact (i.e., not crushed or torn). Always refer to current infection prevention policies for up-to-date information on PPE usage.
  - d) **Note: Employees must wear the N95 respirator that they were fit-tested for.**
  - e) **Employees will conduct a "user seal-check" prior to each use of the N95 respirator. See Appendix F.**
  - f) Priority fit-testing for the N95 is possible for small numbers of personnel that are providing direct care to a patient on All on the non-fit-tested nursing units when the patient cannot be

moved to a fit-tested nursing unit for medical reasons. This decision will be made in collaboration with Infection Prevention, EOHW, and OESO.

- g) Unanticipated use of a N95 respirator without fit-testing is appropriate with an unmasked patient. Patient care areas that have employees that are not fit-tested with the N95 respirator should keep a box of N95 respirators on hand. The seal check described in Appendix F should be performed prior to use.
- 7) PAPRs:
- a) A list of personnel designated as PAPR users can be found in Appendix E.
  - b) PAPRs cannot be used inside a sterile field.
  - c) The PAPR will be used by all employees that fail or are unable to be fit-tested with the N95 mask including those employees with facial hair interfering with the sealing surface of the N95.
  - d) Training on the proper use of the PAPR is required and is provided by OESO. On-line training for the PAPR is available at [OESO's Safety Training Website](#). The module is called "Respirator Training for Airborne Pathogens".
  - e) PAPRs are located in the Equipment Distribution Department and can be ordered through the Service Now Portal. **(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).** The disposable head coverings are ordered from Material Services through SAP (#330895).
- 8) **Note:** Anytime a person wearing a respirator experiences difficulty breathing, chest pain, or other symptoms they should exit the room and remove the respirator. If these symptoms are not relieved, then they should seek medical attention.
- 9) Respirator Approval Process:
- a) Medical clearance initially involves EOHW review of a screening questionnaire. This questionnaire is looking for medical conditions that may preclude respirator usage. Occasionally a person may need to be referred for further medical evaluation. Employees must be re-evaluated for medical clearance if their medical condition changes.

- b) Training includes information on the purpose, proper use (including the “user seal-check”), storage, handling, and limitations of the respiratory protective devices.
- c) N95 respirator fit-testing is required in accordance with OSHA regulations and involves matching a mask type and size to each individual’s face and measuring leakage potential during use conditions. Personnel who have already been fit-tested at another institution within the last year do not need to be retested as long as they can provide adequate documentation and were fitted with one of the respirators available at Duke.
- d) Upon successful completion of medical clearance, annual training, and fit-testing (in accordance with OSHA regulations), each individual is approved to wear a specific respirator (type and size). Employees may only wear the respirator for which they have been approved. **Substitution by manufacturer, size, or model is not allowed.**

10) Monitoring:

Access to respiratory protection compliance summaries will be provided to supervisors and managers. **Failure of designated personnel to comply with the Respiratory Protection Program constitutes a violation of Duke work rules.** Employees can check their compliance with respiratory protection training, fit-testing and medical clearance requirements by logging onto OESO’s Safety Training Website.

## IX. APPENDICES

### Appendix A: County Health Departments & North Carolina Public Health Services

#### 1) County Health Departments

**Tuberculosis is a reportable disease in North Carolina.** NC General Statute (130A-135) requires licensed physicians to report cases and suspected cases of reportable communicable diseases and conditions in persons who have consulted them professionally. **Physicians (or Infection Prevention/PHE at Duke) will forward case reports to the health department of the patient’s county of residence** who will then forward them to the Epidemiology Division, Department of Health and Human Services (DHHS) PO Box 27687, Raleigh, NC 27611-7687.



**Tuberculosis should be reported within 24 hours by phone and form (DHHS 2124).**

Health departments provide the following TB control services regardless of the ability to pay:

- 1) Follow-up of all community contacts and collaboration with other counties as needed.
- 2) Directly observed treatment for active cases.
- 3) Clinic services for patients with TB Complex (nursing, chest x-ray, laboratory, pharmacy, nutrition, and health education).
- 4) **All tuberculosis medication** (TB Complex) for prophylaxis or treatment.
- 5) Tuberculosis testing for anyone that meets the targeted testing criteria.
- 6) Chest x-ray as indicated for anyone with a (+) TST or IGRA.
- 7) TB Complex evaluation of persons with a previous (+) TST or IGRA and one negative chest x-ray.
- 8) Maintenance of a registry of patients with tuberculosis who reside in the respective counties of NC.
- 9) All case reports are reported to NC DHHS.
- 10) Consultation services on active TB cases with the health department in the patient's county of residence.
- 11) After hours and on weekends if consultation is needed call 911 (outside Duke) and ask to speak with the Durham County Health Department (DCHD) supervisor on call.

**2) North Carolina Department of Health and Human Services (DHHS)**

**Tuberculosis is a reportable disease in North Carolina (NC General Statute 130A-135) and requires:**

- 1) **Case Report:** Licensed physicians report cases and suspected cases of reportable communicable diseases and conditions in persons who have consulted them professionally (see above).
- 2) **Laboratory Report:** Each smear positive for acid-fast bacilli and each specimen or culture positive for TB Complex should be reported within seven days of obtaining the result. The completed report is sent to: DHHS, Division of Epidemiology, Tuberculosis Branch, PO Box 27687, Raleigh, NC 276211-7687.
- 3) **Statutes of the State of North Carolina** provide the following for TB control:
  - 1) **Duty to pay:** outpatient treatment paid for by the patient's local health department.
  - 2) **Public health powers to direct:** examination, outpatient care, in-home isolation, or hospitalization for a person with (or suspected) tuberculosis.
  - 3) **Confidentiality:** Protection is provided to the individual, but release of information for statistical purposes, public health control measures, and to medical persons providing care for a patient is enabled.

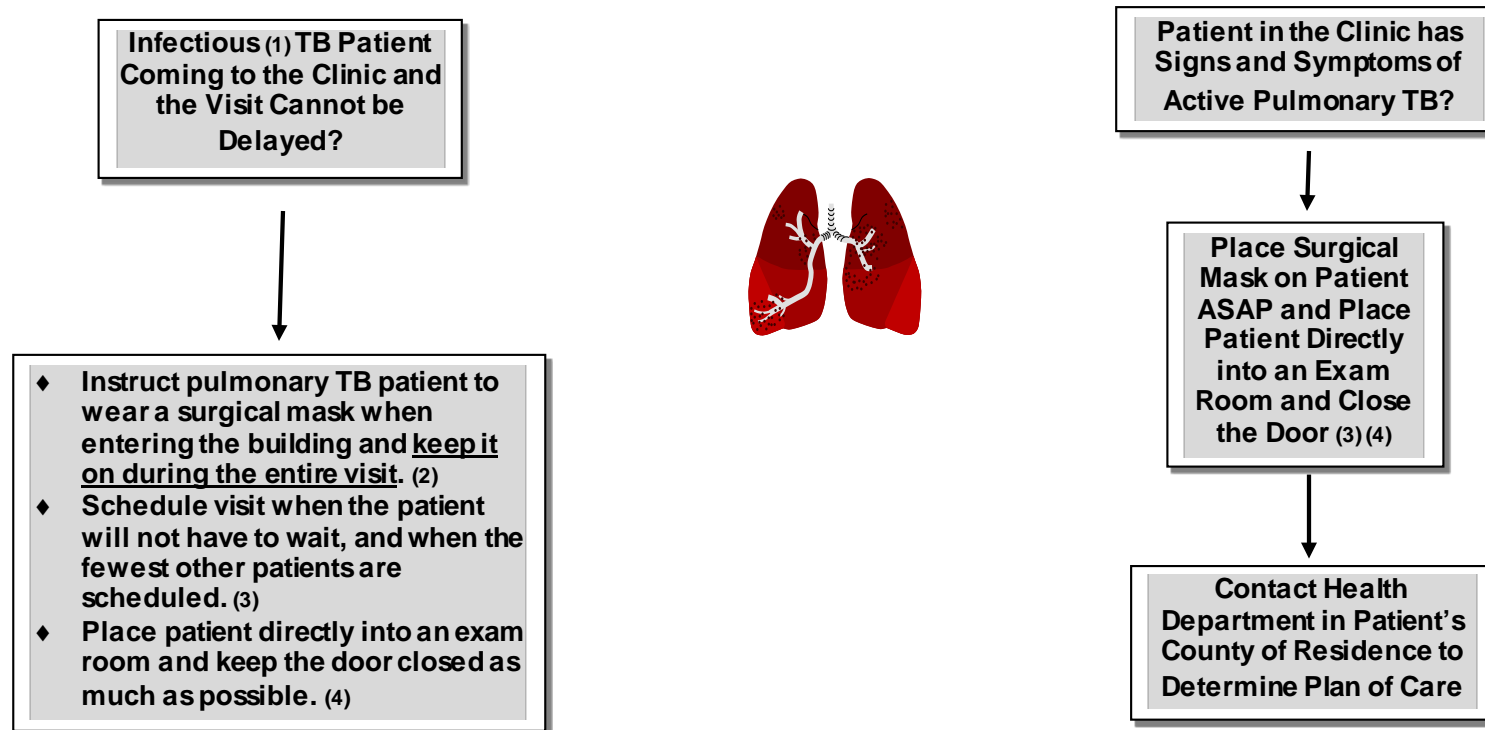
**Note:** a person, by court order, may be held for up to 30 days to determine their clinical and infectious tuberculosis status as a public health precaution. Such a person should have a reasonable possibility of having an infectious form of tuberculosis.

## Appendix B

### Clinic Visits from Known or Suspect TB Patients

Biological Safety/OESO/DUHS 8/2018

[https://www.safety.duke.edu/sites/default/files/TB\\_Patient\\_Clinic\\_Visit\\_Flowchart.pdf](https://www.safety.duke.edu/sites/default/files/TB_Patient_Clinic_Visit_Flowchart.pdf)



- (1) **Pulmonary TB** – Smear positive patients are infectious. Noninfectious is: 2 negative sputum smears (collected at least 8 hours apart; patient is clinically improving; and is on effective drug therapy for 2 weeks). Confer with Health Department in patient’s county of residence to determine this.
  - a. **Wounds or Open Draining Lesions** – Unhealed wounds and lesions are infectious and must be completely covered. Irrigation of unhealed wounds or lesions will produce infectious aerosols and airborne precautions must be taken. Noninfectious is: The patient has been on effective anti-tuberculosis treatment for at least 2 weeks and the wound or lesion is healed.
- (2) Respiratory protection is not needed for the employee if the patient is wearing a surgical mask. In an emergency with an unmasked patient a N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.
- (3) If the exam room is an “Airborne Infection Isolation (AII) Room” perform the tissue test and document results. If the exam room is not an AII room use a portable HEPA if available.
- (4) After discharge, if the patient wore a surgical mask, routine procedures are used to clean the exam room. If the patient did not wear a surgical mask, the room must sit empty with the door closed 30 minutes for AII rooms or rooms that used a portable HEPA, and 60 minutes for other exam rooms. Do not enter the exam room during this time without respiratory protection.

## Appendix C: Airborne Infection Isolation (All) Rooms

### *High-Hazard / Cough-Inducing Procedure Rooms*

<b><u>BUILDING</u></b>	<b><u>FLOOR / DEPT.</u></b>	<b><u>ROOMS</u></b>
DMP	1 / Bronchoscopy	1E94, 1E95, 1W86 (recovery)
Duke Hospital	1 / ED	C40 (1650 I Pod C Adult), Peds 3 (1610 B Coastal)
Duke Hospital	3 / PACU	43, 44, 52, 53
DMP	3 / PACU	17, 18, 19
Children's Health Center	3 / Peds Bronchoscopy	3907A, 3907B
Duke Clinic	2 / Clinic 2A, Adv. Th. Ctr.	25129E, 25129F
Duke Clinic	2 / Clinic 2P, Bronch. Suite	2102, 2103, 2113, 2115, 2116
Duke Clinic	3 / Autopsy	3222E, 3222F
Eye Center Wadsworth Bldg	1 / Clinical Micro Lab	0120, 0184A
Duke Asthma, Allergy, and Airway Center	1821 Hillandale Rd.	Croasdaile

### *Designated All Rooms*

*Patients on All should be placed in one of these rooms whenever possible, unless all these rooms are occupied by patients on All or it is not medically appropriate to place the patient on one of these nursing units. Employees are fit-tested for N95 respirators on these nursing units.*

<b><u>Duke North</u></b>	<b><u>DMP</u></b>	<b><u>DCT</u></b>
2101 (Gen Surgery)	6W 9-16 (SICU)	6DCT 16-17 (Abd Tx)
2332 (Gen Med)	6E 9-16 (CTSD)	
4332 (Gen Med)	8W 13-20 (MICU)	
5101, 5131 (Peds)		
5610 (PICU)		
7822, 7831, 7833, 7834 (Pulmonary)		
8101 (Sleep Lab)		
8332 (Gen Surgery)		

**Back-up All Rooms**

These rooms are to be used only if all possible designated TB All rooms are being used for patients on All or if it is medically necessary that the patient stay on that unit. Contact Infection Prevention (684-5457 or 970-9721) for approval. **Employees not fit-tested** for an N95 respirator must use the PAPR for respiratory protection.

<b><u>Duke North</u></b>	<b><u>DMP</u></b>	<b><u>DCT</u></b>
3101 (CTSD)	7W 13-20 (CT ICU)	1A16 (Peds Surg Serv)
3332 (CTSD)	7E 9-16 (CCU)	1A17 (Peds Surg Serv)
4101 (Gen Med)	8E 9-16 (Med/Surg SD)	2A16 (Peds Surg Serv)
4216 (NICU)		2A17 (Peds Surg Serv)
5509 (NICU)		3A16 (PPCU)
5809 (L&D)		3A17 (PPCU)
6332 (Special Serv)		4A16 (Peds Onc)
7101 (Heart)		7A16 (Neuro ICU)
7332 (Heart)		7A17 (Neuro ICU)
7717 (Cardiac SD)		8A16 (Neuro SD)
9101 (Acute Leuk & Lymph)		8A17 (Neuro SD)
9201		9A16 (Neuro SD)
9332 (Onc)		9A17 (Neuro SD)
		10A16 (BMTX)
		10A17 (Onc/MedSurg)
		11A16 (Ortho)
		11A17 (Ortho)

## Patient Care Airborne Infection Isolation Room Instructions

1. NURSING PERFORMS THE TISSUE TEST EACH DAY that airborne precautions are in place. Local protocols may require more frequent testing. Hold a small piece of tissue in front of the door ~1" above the floor outside of the room. Slightly crack glass sliding doors. The tissue should be pulled towards the room at all doors including the anteroom door/s.
  - ◆ If there is a key switch above the main patient door, it should be set to negative (-).
  - ◆ If there is an air-ball indicator make sure the ball is pulled into the room (unable to see from outside the room).
  - ◆ Document the tissue test result on the "Tissue Test Log for Negative Air Pressure", below. A notebook of these completed forms must be kept in the area or unit.
2. **If the room is not operating correctly or you need assistance call E&O at 684-3232.**
3. CLOSE ALL DOORS AND KEEP THEM CLOSED WHEN ROOM IS IN USE FOR AIRBORNE ISOLATION: This is necessary to maintain negative airflow.
4. PLACE AIRBORNE INFECTION ISOLATION SIGNS ON THE DOORS TO THE PATIENT ROOM AND ANTEROOM. Additional signs can be ordered through the SAP system.
5. STOCK RESPIRATORY PROTECTION IN THE ANTEROOM FOR USE BY EMPLOYEES AND VISITORS:
  - ◆ N95 Respirators
  - ◆ Powered Air Purifying Respirators (PAPRs) for those who are not fit-tested for an N95 (Note: PAPRs cannot be used inside a sterile field):
    - PAPRs are plugged into the charger when not in use.
    - PAPRs can be ordered through the Service Now Portal.
    - ✓ (For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7).
    - Use only appropriate PAPR Head Covers – (Remove film before first time use.)
6. EMPLOYEES WEAR APPROVED RESPIRATORY PROTECTION TO ENTER AIRBORNE ISOLATION ROOM
  - ◆ An annual fit-test by EOHW/OESO is required to use an N95 respirator, otherwise use a PAPR.
  - ◆ Perform a user "seal-check" each time you wear an N95 respirator.
  - ◆ In an emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not (and employee performs and passes user seal check).
7. THE PATIENT SHOULD WEAR A SURGICAL MASK IF TRANSPORT OUTSIDE OF THE ROOM IS ESSENTIAL
  - ◆ Inpatients on airborne isolation are not to leave their room unless medically necessary or Infection Prevention has given approval.
  - ◆ Transporters are not fitted for the N95 respirator. Bring the patient out of the airborne isolation room to them.
8. VISITORS SHOULD WEAR N95 RESPIRATORS (WITHOUT FIT-TESTING)
  - ◆ Nursing should provide instruction to visitors on how to perform the N95 user seal-check and how to properly wear and discard the N95 respirator.
9. NOTIFY INFECTION PREVENTION: 919-684-5457 (or 919-970-9721 after hours)
  - ◆ Infection Prevention can provide guidance on all types of isolation precautions and ensure that the patient location is the best place for the patient.
  - ◆ Infection Prevention will assist with coordinating with the health department in the patient's county of residence as needed.
10. KEEP DOORS CLOSED FOR AT LEAST 30 MINUTES AFTER AN AIRBORNE INFECTION ISOLATION PATIENT LEAVES THE ROOM:
  - ◆ If the patient is discharged while still on isolation or the patient is having a procedure performed elsewhere in the hospital or clinic.
  - ◆ Respiratory protection must be worn to enter the room before this time is up and all the doors must remain closed.



## Appendix E: Personnel Requiring N95 Respirator Fit-Testing

- ♦ Healthcare workers that enter rooms with patients on Airborne Infection Isolation in the following areas (including nurses, PAs, NPs, and EVS workers):
  - 2100
  - 2300
  - 4300
  - 5100
  - 5600
  - 7800
  - 8100
  - 8300
  - DMP 6E
  - DMP 6W
  - DMP 8W
  - 6 DCT
  - Emergency Department (including unit coordinators)
  - Life Flight (all EMS transport personnel)
  - Infectious Disease Clinics - Adult and Peds (CHC)
  - All Pulmonary Clinics – 2F/2G, off-site, and Peds (CHC)
  - Bronchoscopy - Adult, Pediatrics, Clinic 2P (including radiology techs)
  - Oncology Treatment Center – Cancer Center (risk to aerosolized BCG) (supervisor will designate)
  - Advanced Therapeutics Clinic- 2A (non-Oncology infusion)
  
- ♦ Housestaff assigned to work in the following specialty groups/programs:
  - Emergency Department (part of Surgery/Trauma)
  - Infectious Disease (Adult and Peds)
  - Pulmonary Medicine (Adult and Peds)
  - Internal Medicine
  - Combined Medicine and Pediatrics
  
- ♦ MD Faculty in the following specialty groups/programs:
  - Emergency Department (part of Surgery/Trauma)
  - Infectious Diseases (Adult and Peds)
  - Pulmonary Medicine (Adult and Peds)
  - Selected MDs that work in Autopsy
  - Hospitalists (Adult and Peds)
  
- ♦ Respiratory Care and Pulm Func Lab patient-care providers and equipment handlers
- ♦ Radiology patient-care providers in Diagnostic X-Ray (hospital), CT (hospital), U/S (all)
- ♦ All Radiology RNs (on-site)
- ♦ Clinical Microbiology employees working in areas with potential TB aerosols (supervisor will designate)
- ♦ Laboratory staff that assist with bone marrow biopsies (supervisor will designate)
- ♦ Pathology personnel (employees that would perform frozen sections on specimens with a suspicion of tuberculosis)
- ♦ Cytology staff assisting with fine needle aspirates in Bronchoscopy
- ♦ Selected E&O HVAC employees (supervisor will designate)
- ♦ Selected PT/OT employees (supervisor will designate)
- ♦ Vascular Access Team (formerly IV Team)
- ♦ Inpatient Phlebotomists
- ♦ DUHS Float Pool CNAs (serve primarily as sitters)
- ♦ CDU Sonographers & RNs
- ♦ Inpatient Dialysis patient-care providers
- ♦ Perfusionists



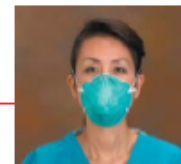
### ***Personnel Designated as PAPR Users***

- Those who fail the N95 fit-test
- Those who have beards or other facial hair that interferes with the fit of the N95
- DUHS Float Pool RNs & CMAs
- Inpatient Dialysis HCWs (RNs, NCAs, Techs)
- Autopsy Techs
- Hospital-based ECG technicians (Heart Station)
- Physiological Monitoring Cardiology Techs (Central Telemetry)
- Neurodiagnostics Techs
- Patient Advocates
- Interpreters (International Patient Center)
- Selected Pastoral Care employees (supervisor will designate)
- Social Workers
- Case Managers
- Speech Pathology Staff
- Low-risk Radiology on-site departments:
  - Clinic-Based Diagnostic X-Ray (2E, 1B/1C, 1G, 1H & CC), Clinic-Based CT (CC), Pet Scan, Nuclear Med, Peds
  - Note: MRI Techs & Mammography are not classified as needing respiratory protection

# Wear It Right

## 3M™ Respirators

Appendix F



### 3M™ 1860/1860S Health Care N95 Particulate Respirator and Surgical Mask

#### APPLICATION:



**1** Cup the respirator in your hand with the nosepiece at fingertips, allowing the head straps to hang freely below hand.



**2** Position the respirator under your chin with the nosepiece up.



**3** While holding the respirator in place, pull the top strap over your head so it rests high on the back of your head.



**4** While continuing to hold the respirator firmly in place, pull the bottom strap over your head and position it around your neck, below your ears. Untwist the straps. Position the respirator low on your nose.



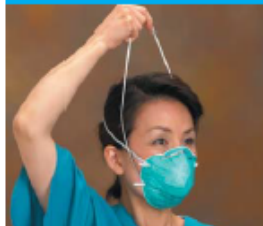
**5** Using both hands, mold the nosepiece to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. **Note: Always use two hands when molding nosepiece.** Pinching with one hand may result in improper fit and less effective respirator performance.

#### POSITIVE PRESSURE FIT CHECK

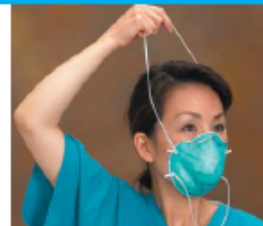


**6** The respirator must be checked before each use. To perform the fit check, place both hands completely over the respirator, being careful not to disturb the position, and exhale sharply. If air leaks around your nose, adjust the nosepiece as described in step 5. If air leaks at respirator edges, adjust the straps back along the sides of your head. Perform fit check again if an adjustment is made. If you cannot achieve a proper fit, see your supervisor. Do not enter area requiring respirator use.

#### REMOVAL:



**1** Without touching the respirator, slowly lift the bottom strap from around your neck up and over your head.



**2** Lift off the top strap. Do not touch the respirator.



**3** Store or discard according to your facility's infection control policy.

**3M Health Care**  
3M Center, Building 275-4W-02  
St. Paul, MN 55144-1000  
U.S.A.  
1 800 228-3957

[www.3m.com/healthcare](http://www.3m.com/healthcare)

**3M Canada**  
Post Office Box 5757  
London, Ontario N6A4T1  
Canada  
1 800-563-2921

Outside of USA, please contact your 3M Representative

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70-2009-0557-1



#### WARNING

This respirator helps protect against certain particulate contaminants, but does not eliminate exposure to or risk of contracting disease or infection. Misuse may result in sickness or death. For proper use, see your supervisor or call 3M Occupational Health and Environmental Safety Division Technical Services at 1-800-243-4630.

## Appendix G: Management of Known and Suspect TB Patients in the Operating Rooms (Duke Hospital and Duke Medicine Pavilion)

- 1) Because the Operating Room (OR) has recirculated air under positive pressure, surgery on patients with known or suspected TB should be postponed until TB has been ruled out or the patient is determined to no longer be infectious.
- 2) If surgery cannot be postponed then a portable HEPA must be placed in the room from the time the patient enters the room until a minimum of 30 minutes after final cleaning. In Duke Hospital OR use one portable HEPA per suite and in the DMP OR use two portable HEPAs per suite. The portable HEPAs should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)).
- 3) The case should be scheduled as the last case of the day.
- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) All employees entering the room or enclosed area must wear N95 respirators (or a PAPR if that employee only works outside the sterile field). Since the OR is an area of low risk for TB transmission, fit-testing for the N95 respirator is not routinely required for the OR staff. In cases that suspicion for TB arises during surgery staff should replace their standard surgical masks with an N95 respirator without fit-testing. The N95 respirator provides acceptable temporary protection whether the employee is fit-tested or not (if employee performs and passes user seal check). In cases where TB is suspected before the surgery, every effort will be made to identify those staff that will be working in the particular OR suite and provide them with N95 respirator fit-testing prior to the procedure.
- 6) During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended ventilation standards for TB isolation rooms (PACU isolation rooms are listed in Appendix D) or remain in the Operating Room with the portable HEPA filter still running.
- 7) The following ICU level isolation rooms are on a designated All unit: DMP 8 West (MICU) rooms 9 – 16, and DMP 6 West (SICU) rooms 9 – 16. *If medically the patient requires the specialized care of one of the other intensive care units then one of the following*

*ICU level isolation rooms may be used: DMP 7 West (CT ICU) rooms 13 – 20, 7 East (CCU) rooms 13 – 20.*

- 8) In cases of known multi-drug resistant tuberculosis that require surgery, contact Biological Safety (919-684-8822) for coordination of additional engineering controls to be implemented by the Engineering and Operations HVAC division. Also contact EOHW/OESO to arrange for N95 respirator fit-testing for those employees working within the sterile field. The details for this protocol can be found in the Operating Room Safety Manual.

## **Appendix H: Management of Known and Suspected Tuberculosis (TB) Patients in the Cardiac Catheterization, Electrophysiology Laboratories, and Radiology Invasive Procedure Rooms**

- 1) Procedures on patients with known or suspected TB should be postponed until TB has been ruled out or the patient is determined to no longer be infectious.

If the procedure cannot be postponed then a portable high efficiency particulate air (HEPA) filter must be placed in the room from the time the patient enters the room until after the room has been cleaned following the case, a minimum of 30 minutes after final cleaning. The portable HEPA filter should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). Portable HEPAs are ordered through the Service Now Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-2072, 24/7)*

- 3) The case should be scheduled in an enclosed room and doors should be kept closed. The case should be scheduled as the last case of the day.
- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) All employees entering the room or enclosed area must wear N95 respirator masks (or PAPRs if that employee only works outside the sterile field). In areas of low risk for TB transmission routine fit-testing for the N95 respirator is not required. In cases whereby suspicion for TB arises during a procedure, staff should replace their standard surgical masks with an N95 respirator without fit-testing. A user seal-check should always be performed when donning an N95. The N95 respirator provides acceptable temporary protection whether the employee is fit-tested or not (if **employee performs and passes user seal check**). In cases where TB is suspected before the procedure, every effort will be made to identify those staff that will be working that particular case and, if they are not fit-tested within the past year, provide them with N95 respirator fit-testing prior to the procedure.
- 6) During transport the patient is to wear a surgical mask. If possible, and the patient is not intubated, the patient is to wear a surgical mask during the entire procedure.

## X. References

- A. Occupational Safety and Health Administration Respiratory Protection Standard [29 CFR 1910.134](#)
- B. Duke University Health System's [Safety Manual Respirator Policy](#)
- C. [The Respiratory Policy for TB, SARS, and Other Airborne Particulates in Clinical Settings](#)
- D. Centers for Disease Control and Prevention, "[Guidelines for Preventing the Transmission of \*Mycobacterium tuberculosis\* in Health-Care Settings, 2005](#)"
- E. Centers for Disease Control and Prevention, "[Core Curriculum on Tuberculosis, What the Clinician Should Know](#)" Fourth Edition, 2000"
- F. NC TB Control Program Policy Manual [NC DPH: N.C. Tuberculosis Policy Manual](#)
- G. Centers for Disease Control and Prevention, MMWR/May 17, 2019/Vol.68/No.19, "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019"