TUBERCULOSIS 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

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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 equipment such as a respirator mask. 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 or non-human primates.

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 health care workers and patients with known or suspected exposure to Mycobacterium tuberculosis (M. tuberculosis).

B. EOHW will provide reports to the Hospital Infection Control Committee (HICC) quarterly that include, along with appropriate demographic information, the number of hospital employees with known or suspected occupational exposure to TB, the number of employees who had a tuberculin skin test (TST) and their baseline status, the number of employees who converted their TST
after a known or suspected exposure to a patient with active tuberculosis, and
the number of employees with suspected exposure who were lost to follow-up.

C. EOHW will maintain records on all tuberculin skin tests done on new
employees and tuberculin skin testing of current employees (including post-
exposure tuberculin skin testing). In an annual written report to the HICC, EOHW
will summarize, including appropriate demographic information, the following
data:

1) Current employees who had annual TST screening.

2) Employees who have had a TST conversion.

D. Biological Safety will annually summarize the following in written reports
provided to Infection Prevention, QESO, EOHW, and Engineering and
Operations; and will present this information to HICC:

1) The TST conversion incidence by job location and/or job description
(whichever is more appropriate). This information is provided to
Biological Safety by EOHW and will be used for risk assessment.

2) The total number of days of isolation for:
   a) tuberculosis, and
   b) suspected tuberculosis

3) An analysis of nosocomial tuberculosis exposures and any evidence of
trends or unusual circumstances. Individual cases will be investigated
and reported describing the factors leading to such exposures with
recommendations for preventing future exposures whenever possible.

F. Biological Safety will assess the potential of occupational exposure to TB
for all employees of Duke. 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 *M. tuberculosis*.

1) Work assignment for all or part of the employee’s scheduled work
time in areas where there is a risk of exposure to TB aerosols (e.g.,
patient care areas/buildings). New hires to these areas are
evaluated by EOHW for infection with *M. tuberculosis*. 
2) Work assignment is in a high risk area and employee is an N95 respirator user (See Section VIII F).

3) Work assignment is in a high risk area and employee is a PAPR respirator user (See Section VIII F).

4) Work assignment is in a high risk area and employee is evaluated annually by EOHW for infection with *M. tuberculosis* (See Section V F).

5) No EOHW requirement.

6) Works with non-TB mycobacteria.

7) Non-clinical work assignment for all or part of the employee’s scheduled work time in areas where there is a risk of exposure to TB aerosols (e.g., patient care areas/buildings). New hires to these areas are evaluated by EOHW for infection with *M. tuberculosis*.

8) “Special EOHW Review” – annual TB Questionnaire with EOHW review for those employees with latent TB infection, not in a high risk area/group for TB exposure.

**Animal Contact:**

0) No exposure.

1) Animal contact.

2) Works with non-human primates.

3) On protocol – no animal exposure.

**IV. RESPONSIBILITIES**

**A. Employees**

1) All employees with exposure determinations of Airborne Pathogens1 – 4, 7, 8, and Animal Contact 2 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 and Animal Contact 2 must comply with the requirements of the Respiratory Protection Program Policy for TB (see Section VIII F).
2) Employees will conduct a “user seal-check” prior to each use of the N95 respirator mask.

3) Employees will report any incidents of possible exposure to tuberculosis to Infection Prevention, EOHW, or Biological Safety.

B. Department Managers

1) Document each of their employees’ compliance with the Duke’s tuberculosis policies (including the Division of Laboratory Animal Resources policies and procedures) and compliance with OESO Biological Safety tuberculosis educational programs on their yearly performance evaluation.

2) Enforce the requirements of this plan.

3) Assist EOHW in the scheduling of any training, fit-testing, medical evaluations, or any other activity relating to compliance of this program.

4) Assist OESO in identifying areas and job tasks at risk.

5) Assure that appropriate respiratory protection is available in facilities that house non-human primates.

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 finding to the Executive Committee of the Medical Staff.

2) The Chairman 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 Chairman of the HICC has the responsibility and authority to mandate specific isolation should disagreement occur between Duke Hospital and Clinics physicians and personnel from Infection Prevention or the PHE.

3) The Chairman 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 TB Exposure Control Plan at least annually.

D. Infection Prevention

1) Assure compliance with the Duke policies as to the initiation and discontinuation of Airborne Infection Isolation (AII) 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 AII. On-call advice is available 24 hours a day, 7 days a week by calling Infection Prevention at 684-5457 or pager 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 control plan annually.

4) Report or assist in reporting all cases of known or suspected tuberculosis to the patient’s county of residence health department. 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 *M. tuberculosis* 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 F)

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 Safety Committee as needed.

4) Provide, document, and be responsible for any OSHA-required TB control training programs at Duke. This includes training at orientation and annual update training. All employees with exposure determination ratings of Airborne Pathogens 1 through 4, 7 and 8, and Animal Contact 2 shall receive annual education concerning tuberculosis control. Those employees with exposure determinations of Airborne Pathogens 2 or 3 and Animal Contact 2 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 E&O).

6) Assure that appropriate respiratory protection is available on all units caring for a patient on All for TB.

7) Identify potentially exposed employees and students and provide this list to EOHW or Student Health, respectively, for further evaluation.

8) Manage and conduct annual reviews of the Respiratory Protection Program Policy for TB.

F. Employee Occupational Health and Wellness (EOHW)

1) New Employee Screening – New employees who will receive a medical placement health review will be evaluated for:

a) Prior TB history and any previous therapy for tuberculosis.

b) Prior TST placement (to include dates of the most recent negative or positive TST and any known prior TST conversion).

c) Prior therapy for active or latent tuberculosis including dates, types of treatment and results of prior chest radiographs.

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 physician.
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 all employees with potential exposures (see Section VI).

4) Periodic screening of employees (see Section V).

5) Implement the Respiratory Protection Program Policy for TB (Section VIII F).

G. Duke Student Health Service

1) All Duke medical students and other allied health students will have tuberculosis testing, TST or IGRA, depending on risk factors, within 12 months prior to matriculation.

2) All Duke medical students and other allied health students are required to have annual tuberculosis testing.

3) 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).

4) Students have six weeks following notification of the need for post-exposure tuberculin testing in which to record a current tuberculin test result with Duke Student Health. A second test will be required approximately 8 – 10 weeks after exposure. Noncompliant students will be restricted from clinical rotations by their respective Health Science Program.

5) 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.

6) 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 *M. tuberculosis* isolation, identification, and susceptibility testing in the CMB Laboratory, 108 CARL building. Routine AFB smears and cultures will be done weekdays. The CMB Laboratory will report all positive *M. tuberculosis* test results to Infection Prevention and forward these results to the NC Department of Health and Human Services, (Form DHHS 3005 [8/99]).

2) CMB will provide an annual report to Biological Safety summarizing all isolates of *M. tuberculosis* and their susceptibilities.

3) **Positive Smear Results and Positive Identification of TB Complex**

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

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

b) the first positive identification of *Mycobacterium tuberculosis* complex (e.g., *Mycobacterium tuberculosis*, *Mycobacterium bovis*, and *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 Infection Prevention, and the North Carolina public health system.

2) The Autopsy Service will notify Infection Prevention when thick-walled cavitary 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 cavitary 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. TUBERCULIN SKIN TESTING

A. Tuberculin skin testing is used to screen new employees working in patient care areas or buildings, to screen new unpaid workers (e.g., volunteers, providers, and observers), for periodic employee surveillance, after potential employee exposures to TB and for screening of employees and contractors working with non-human primates. Student Health performs annual TB testing on all PA, PT and nursing students. Medical students are tested prior to matriculation, at the beginning of 2nd year and in March prior to graduation. Annual TB testing is also required of all students volunteering in the Health System. Additionally, all healthcare contract workers must comply with Duke Policy through their respective agencies prior to job placement.

B. EOHW and Student Health will provide annual summaries of tuberculin skin testing with documentation of any TST conversions to Biological Safety/OESO.

C. A TST will be placed 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 E) 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) Documentation of allergy (i.e., immediate hypersensitivity) to TST reagents.

4) Documented as currently receiving anti-tuberculosis therapy.

5) Documented negative test within the last 90 days.

D. Employees will be questioned 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.

E. A standard TST will employ 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).

A repeat TST (two step testing) will be done on individuals in the following groups who have not had a documented test within twelve months. Repeat testing will apply when the first test is negative:

- 55 years of age or older
- Coming from an area with a high prevalence of TB
- Have a history of BCG but no documentation of a positive tuberculin test.
- Equivocal prior test results.

Thereafter, such individuals will have annual tuberculin skin testing according to their work environment risk evaluation.

F. 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) The employee is a foreign-born person from a high prevalence country such as Asia, Africa, Latin America, or countries that were in the former Soviet Union.

  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.

**G. Periodic Employee Surveillance:**

1) Employees with negative tuberculin test:

   Personnel with exposure determinations of Airborne Pathogens 4 and/or Animal Contact 2 will be tested annually.

2) Employees with positive tuberculin test or contraindication to TST:

   a) Personnel categorized and working in areas requiring annual TB testing with prior positive tuberculin reactions or those who
cannot take the TST for other medical reasons will be assessed for testing with IGRA. Those with LTBI 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).

b) Employees with positive tuberculin skin tests who have completed a full course of preventative therapy that is acceptable by the CDC require an annual TB evaluation by EOHW for signs and symptoms of active TB disease.

3) Employees who are new converters:

a) All employees with documented recent TST conversion will be counseled by EOHW and have the following tests:

i. Chest x-ray.

ii. 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.

iii. HIV testing.

b) INH prophylaxis (or other alternate therapies) will be recommended for all recent tuberculin converters consistent with current recommendations of the CDC/USPHS and the Tuberculosis Advisory Group.

c) Employees who are recent converters who are placed on preventative therapy with INH (or other alternate therapies) will be treated according to recent CDC recommendations and guidelines.

d) If no drug prophylaxis is given for LTBI and conversion is within two years, a chest x-ray is repeated after 18-24 months.

4) Treatment of employees with active tuberculosis:

a) 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.

b) 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.

H. Employees who are prior BCG vaccine recipients will be evaluated and tested in the same manner as other employees. If their TST is positive, IGRA may be considered in these cases as confirmatory tests for healthcare workers who have had a BCG vaccine and positive TST. If the IGRA is negative, and if the employee is part of a work-group that requires surveillance, then IGRA will be used for future monitoring.

I. 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 *M. tuberculosis* 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 contact with a patient or non-human primate with infectious tuberculosis and adequate AII precautions were not utilized or other exposure to TB aerosols.

A. Infection Prevention will notify OESO when a patient with infectious tuberculosis has been admitted to the hospital or seen in the clinics in whom AII was inadequate. 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 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 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 AII 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 TST 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 tuberculin skin testing. Employees have three weeks post notification to respond or their department director or chairperson will be notified. Any employee who has not had tuberculin test results recorded in EOHW within six 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 TST 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 should be repeated 8-10 weeks later.

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 an area that is high risk for TB 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 1-4, 7 and 8, and Animal Contact 2:

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) The rationale and necessity of annual tuberculin skin testing in high-risk areas, the potential significance of a positive TST and the responsibility and obligation to participate in annual tuberculin skin testing programs.

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
VIII. MANAGEMENT OF PATIENTS WITH KNOWN OR SUSPECTED TUBERCULOSIS

A. Recognition of Patients with Potential Tuberculosis Infection

1) Diagnosis of tuberculosis should be considered in any patient with unexplained prolonged cough or complaints such as hemoptysis, night sweats, weight loss, or fever in whom an alternate diagnosis has not been established or thought to be highly likely. All patients with suspected tuberculosis should be placed in AII in a designated isolation room by their primary health care givers until active infectious tuberculosis is excluded. It is the responsibility of the physicians and nurses caring for individual patients to assess for signs and symptoms of tuberculosis and to initiate AII for suspected and/or known cases of TB. Questions concerning the medical or epidemiological rationale for continuing such isolation should be forwarded to Infection Prevention.

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 which 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) **Signs and Symptoms of Active 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

4) Appropriate diagnostic studies should be conducted on all patients with suspected tuberculosis. These studies may include tuberculin skin testing; collection of sputum, smears, and cultures (initially three consecutive sputum specimens collected at least eight hours apart, one of which should be an early morning specimen); and chest radiography. In selected instances, bronchoscopy, the induction of sputum for microbiologic studies, nasogastric aspirations (for pediatric patients), and/or bone marrow biopsy may be undertaken. All initial specimens from any source should have cultures performed. Drug susceptibility testing should be done on all initial isolates.

5) When patients with previously diagnosed tuberculosis are admitted to Duke before there is microbiologic and/or clinical confirmation of cure, AII must be utilized pending further assessment and evaluation of their infectiousness. Questions concerning prior TB treatment at the patient’s county health department should be directed to Infection Prevention at 684-5457 Monday-Friday. On weekends or holidays when the Public Health Department is closed, place the patient on AII and contact the Infection Prevention nurse on call.

**B. Inpatient Precautions for Patients**

1) All patients with known or suspected pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain *M. tuberculosis*) will be placed in AII in an appropriately ventilated isolation room (described in detail in Section VIII D 1) **and Infection Prevention will be notified**. This isolation will include admission to a designated isolation room and the wearing of proper protective respiratory devices by all persons entering the patient’s room. Proper protective respiratory devices are described in detail in Section VIII F, and include N95 respirator masks for those employees who are fit-tested by EOHW and Powered Air Purifying...
Respirators (PAPRs) for those who are not fit-tested. See Section VIII G for instructions on ordering PAPRs from Equipment Distribution. Bacterial/viral filters will be used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.

**Visitors** are to wear N95 respirator masks 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 respirator masks and how to perform a user seal-check (see appendix G) before allowing the visitors to enter the patient’s room. Visitors with beards, mustaches, or are unable to achieve a tight seal during the seal check should be shown how to wear a PAPR.

**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.

2) 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 All room for the area they are in (these are the back-up isolation rooms listed in Appendix D and are located throughout the hospital). Designated All rooms and back-up All rooms have negative airflow capability and dedicated exhaust.

3) 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 filter (HEPA) will be placed in the patient room (refer to Section VIII D 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 Maestro or the Equipment Request Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 681-2072, 24/7).* Infection Prevention should be notified of this room decision when housing patients.

4) **All is required for:**

   a) Patients presenting with signs and symptoms of TB, (see Section VIII A). 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. Also, if a patient that presents with only one or two of these signs and symptoms of TB and belongs to one of the groups that are at high-risk for TB, then suspicion for active TB should be raised (see Section VIII A).

b) Patients with Polymerase Chain Reaction (PCR) results positive for TB complex.

c) 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. If M. tuberculosis complex is identified, the drug susceptibility pattern of that isolate must be determined before AII is discontinued regardless of any subsequent smear results.

d) AII is required for any patient with active multi-drug resistant tuberculosis (MDR-TB). Isolation may not be discontinued without approval from an Infectious Disease physician.

5) Infection Prevention will ensure the use of proper precautions. OESO will assure that appropriate respiratory protection is available and will monitor ventilation status.

6) AII may be initiated by attending physicians, consulting physicians, triage nurses, inpatient nurses, physician assistants, nurse practitioners, the PHE, or Infection Prevention personnel. (All 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 AII.)

7) Patients placed in AII will be instructed by the patient’s medical and nursing staff on the need to adhere to AII policies and to cover their mouth and nose with tissues when coughing and sneezing. Patients are to stay in their AII rooms until tuberculosis has been ruled out. (See # 9 below for the criteria required to discontinue isolation.) The only time a patient may leave their room is if a diagnostic procedure must be performed outside of the AII room. Patients who refuse to adhere to AII will be reported to the Durham County Health Department (Appendix A). Legal action may be taken to enforce appropriate AII precautions when requested by the attending physician, the PHE, or Infection Prevention. The Duke Public Safety Office will assist local law enforcement as needed in enforcing court-ordered isolation.
8) In the event that a patient with known or suspected tuberculosis 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 AII room while the patient is wearing a mask. In instances where diagnostic testing must be done outside the AII 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 AII. A procedure request form should indicate the need for AII.

9) Discontinuation of All

a) **A physician order is required to discontinue AII, along with the appropriately documented rationale for the decision.**

b) **For patients suspected of active pulmonary TB, or patients with positive AFB smears where TB is not considered likely, AII may be discontinued following two negative PCR results for TB complex.**

c) Patients with **confirmed** active pulmonary or laryngeal tuberculosis who have **sputum smears positive for AFB are considered infectious and must be kept on AII until:**

   - They have two consecutive sputum smears collected at least eight hours apart which are negative. These specimens are not to be collected until after at least 14 days of treatment and the last smear positive specimen should have been collected at least 7 days previously to the two negative sputum smears; AND
   - They have been compliant on tuberculosis medications to which the organism is judged to be susceptible for at least 14 days of therapy; AND
   - There is evidence of clinical response to tuberculosis treatment.

d) In instances in which an alternate diagnosis has not been established, and TB is still considered in the differential diagnosis, **AII may be discontinued under the following circumstances:**

   - The patient has two consecutive sputum smears collected at least eight hours apart which are negative; AND
The patient has been compliant for at least 14 days on tuberculosis medications to which the organism is judged to be susceptible; AND

There is evidence of clinical response to tuberculosis treatment.

e) All is not required for patients admitted with a diagnosis of “rule out tuberculosis” if that diagnosis is considered an unlikely but theoretically possible diagnosis (i.e., patients who are currently not coughing and who simultaneously do not have cavitary lung lesions suggestive of tuberculosis); AND this is documented in the Medical Record by the physician.

f) When an alternate diagnosis to tuberculosis is either confirmed or deemed highly probable, the attending physician will document the findings and the supportive data in the patient’s medical record.

g) For children or other patients in whom adequate sputa cannot be obtained, All may be removed if:

   ♦ An alternate diagnosis or explanation of symptoms exists;
   ♦ An evaluation by Infectious Diseases has deemed TB unlikely.

h) All may be discontinued for patients with soft tissue or open draining TB lesions when the wound is either no longer draining or the draining material no longer contains acid-fast material on at least two occasions and the patient is on effective anti-tuberculosis chemotherapy.

i) Under special circumstances, All may be discontinued at the discretion of the Chairman of the HICC.

10) Discharge Planning Criteria

a) Unless discharged to an institution with All facilities or home with the restrictions as required by the Health Department in the patient’s county of residence, discharge of institutionalized patients with active TB requires a minimum of two criteria: initial therapy with a minimum of four anti-tuberculosis drugs until susceptibility test results are known, and at least two negative AFB smears collected at least eight hours apart with specimens collected after 14 days of anti-tuberculosis drugs.
Contact the health department in the patient’s county of residence no less than 48 business hours before a patient with active tuberculosis is discharged (see Appendix A). The PHE or Infection Prevention will provide assistance to the Patient Resource 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.

b) Patients who may be infectious at the time of discharge should only be discharged to other facilities with All capabilities or to home. They should not be discharged to home while considered infectious if there are persons in the household who are at high risk of acquiring active tuberculosis (such as children less than five years of age or persons infected with HIV or others who are severely immunocompromised).

c) 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.

C. Outpatient Management of Patients (Refer to Appendix B for Clinic Flowcharts)

1) For all clinics:

   a) Notify Infection Prevention when patients are placed on All for known or suspected tuberculosis in the clinics. Infection Prevention and Biological Safety will provide advice concerning the use of proper precautions and will ensure that confirmed employee exposures are evaluated.

   b) If a patient with known or suspected infectious pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain or are suspected of containing *M. tuberculosis*) must be seen in an outpatient clinic and the visit cannot be rescheduled to a time when the patient is no longer considered infectious, the clinic should be notified prior to the patient’s arrival.

   c) The patient should be instructed to wear a surgical mask 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. If the patient can wear a surgical mask during their entire visit employees do not need to take respiratory precautions.

d) If the clinic is not equipped to handle TB patients (employees are not fit-tested and ventilation is not adequate) and the patient cannot wear a surgical mask during the entire visit, consider referring the patient to a clinic that is equipped to handle TB patients, an Emergency Department, or the health department in the patient’s county of residence. Ventilation time for exam rooms under these circumstances is one hour with the door closed.

e) Patients are no longer considered infectious if they meet all three criteria that follow:

- They have two consecutive sputum smears collected at least eight hours apart which are negative. These specimens are not to be collected until after at least 14 days of treatment and the last smear positive specimen should have been collected at least 7 days previously to the two negative sputum smears; AND
- They have been compliant on tuberculosis medications for at least 14 days to which the organism is judged to be susceptible; AND
- There is evidence of clinical response to tuberculosis treatment.

f) 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.

2) 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 D 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 Maestro or the Equipment Request Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 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 F and include N95 respirator masks for those employees who are fit-tested by EOHW and Powered Air Purifying Respirators (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 Maestro or the Equipment Request Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 681-2072, 24/7).* The disposable head coverings are ordered from Material Services through SAP # 330895. In a medical emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.

3) **For off-site clinics:**

a) Before the patient arrives confirm that the patient is no longer infectious or reschedule the visit if medically possible.

b) If the suspicion of infectious TB disease is discovered during a clinic visit place a surgical mask on the patient as soon as possible. Contact a clinic equipped to handle TB patients (fit-tested employees and portable HEPAs), a local Emergency Department, or the health department in the patient’s county of residence and make plans to refer the patient. 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 mask is acceptable temporary protection whether the employee is fit-tested or not.

4) **Emergency Medical Service:**

a) 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.
b) If the patient is on AII the drivers and other employees present in the enclosed vehicle with the patient must wear appropriate respiratory protection (see Section VIII F).

c) 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.

D. Engineering Controls

1) All Rooms – Inpatient (Refer to Appendix E 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 by the care nurse of any patient on All using the tissue test and documented on the “Daily Negative Air Pressure Test Log” (see Appendix E). This log is maintained on each nursing unit. 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 D) 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 Filter Units

On-site, 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 who are hospitalized in the Labor and Delivery areas, the Operating Room, the Ambulatory Care areas, the Outpatient Clinics, the Radiology departments, and the Interventional Cardiac
Catheterization Laboratory or any area where such patients may be housed 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 HEPA operating instructions are available from Equipment Distribution through Maestro or the Equipment Request Portal. (For immediate needs or emergent situations call the Equipment Distribution Hotline at 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.

E. 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 in rooms that meet the ventilation requirements as outlined for All rooms (Section VIII D 1 and Appendix D). If such rooms are not available, supplemental control devices such as isolation booths or portable HEPA operating instructions must be employed (refer to Section VIII D 2. for information on portable HEPA operating instructions). Portable HEPA operating instructions 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). 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. 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. Employees must wear respiratory protection while cough-inducing procedures are performed on patients with known or suspected tuberculosis (see Section VIII 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 room. After the patient leaves the treatment or procedure room, the room air should be given time to turn over prior to the next patient being placed in the room. 30 minutes should be adequate for most treatment rooms. During this time, the door should remain closed, employees should wear appropriate respiratory protection when entering the room and the portable HEPA should be left running during this time.

2) Aerosol-Generating Procedures:

a) Autopsy rooms should meet the criteria for AII rooms in Section VIII D 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 should be worn by personnel while performing autopsies on deceased persons who may have had TB at the time of death (see Section VIII F).

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

F. Respiratory Protection

1) All employees must wear an appropriate respiratory protection device to enter an enclosed area where a known or suspected tuberculosis patient or non-human primate 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. Appropriate respiratory protection must also be worn by personnel mixing or administering BCG outside of a Biological Safety cabinet.

3) Appropriate respiratory protection is worn by all personnel performing or exposed to TB aerosol-generating procedures in the autopsy suite or in the laboratory and those Engineering and Operations HVAC employees who may be exposed to TB aerosols in the air handling system.

4) The Respiratory Protection Program for TB is administered by EOHW and Student Health.
Background: In October 1994 the CDC published “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities”, which 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 *M. tuberculosis* 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. 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 mask. This TB-specific program is implemented through EOHW.

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 AII onto the designated TB nursing units (4300, 5100, 7800, 8100, 8300, and DMP 6 East). Personnel included in the program will include, but are not limited to, personnel listed in Appendix F that may have direct contact with a patient on AII or the potential to be exposed to TB aerosols generated during high hazard procedures.

5) The N95 respirator mask (N95):

a) A list of personnel requiring N95 respirator fit-testing can be found in Appendix F. Employee fit-testing for airborne pathogens is performed by EOHW. Students needing respiratory protection are fitted in Student Health.

b) 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.

b) Training on the proper use of N95’s is required and is provided by Biological Safety. 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 AI. 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 mask cannot be used between patients. It can be re-used 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).

d) It is important to note that these respirators are authorized for use in protecting employees from TB droplet nuclei.

e) N95 respirator masks can be ordered from Material Services through SAP:
   - SAP #14174 Technol medium, orange, “duck-billed” mask
   - SAP #14173 3M medium, green, molded mask
   - SAP #26378 3M small, green, molded mask

f) **Note:** Employees must wear the N95 respirator mask that they were fit-tested for.

g) Employees will conduct a “user seal-check” prior to each use of the N95 respirator mask. See Appendix G.

h) Priority fit-testing for the N95 is possible for small numbers of personnel that are providing direct care to a patient on AI 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 and EOHW.

i) In a medical emergency with an unmasked patient a N95 respirator mask is acceptable temporary protection whether the employee is fit-tested or not. Patient care areas that have employees that are not fit-tested with the N95 respirator mask should keep a box of N95 respirator masks on hand. The seal check described in Appendix G should be performed prior to use.

6) PAPRs:

a) A list of personnel designated as PAPR users can be found in Appendix F.
b) The PAPR will be used by all employees that are not fit-tested with the N95 mask including those employees with facial hair interfering with the sealing surface of the N95.

c) Training on the proper use of the PAPR is required and is provided by Biological Safety. On-line training for the PAPR is available at OESO's Safety Training Website. The module is called “Respirator Training for Airborne Pathogens”. Biological Safety can be paged at 970-2780 for assistance in utilizing the PAPRs.

d) PAPRs are located in the Equipment Distribution Department and can be ordered through Maestro or the Equipment Request Portal. (For immediate needs or emergent situations call the Equipment Distribution Hotline at 681-2072, 24/7). The disposable head coverings are ordered from Material Services through SAP (#330895).

7) **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.

8) Respirator Approval Process

   a) Medical clearance initially involves 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 basic information regarding TB as taught through the initial orientation and annual update safety training programs, as well as information on the purpose, proper use (including the “user seal-check”), storage, handling, and limitations of the respiratory protective devices.

   c) 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 masks 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.**

9) 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](#).
APPENDICES
Appendix A: Durham County & North Carolina Public Health Services

1) Durham County Health Department (DCHD)

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 @ 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) P. O. Box 27687, Raleigh, NC 27611-7687. Tuberculosis should be reported within 24 hours by phone and form (DHHS 2124).

The DCHD provides the following TB control services regardless of the ability to pay:

1) Follow-up of all contacts of Durham County cases and collaboration with other counties as needed.

2) Directly observed treatment for active cases.

3) Clinic services for patients discharged with *M. tuberculosis* (nursing, chest x-ray, laboratory, pharmacy, nutrition, and health education).

4) All tuberculosis medication (*M. tuberculosis*) for prophylaxis or treatment.

5) Tuberculin skin testing for anyone.

6) Chest x-ray as indicated for anyone with a (+) TST.

7) *M. tuberculosis* evaluation of persons with a previous (+) TST and one negative chest x-ray.

8) Maintenance of a registry of patients with tuberculosis who reside in Durham County.

9) All Durham County residents' case reports are reported to NC DHHS.
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 *M. tuberculosis* should be reported within seven days of obtaining the result. The completed report is sent to: DHHS, Division of Epidemiology, Tuberculosis Branch, P.O. Box 27687, Raleigh, NC 27621-7687.

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.
Clinic Visits from TB Patients –
Hierarchy of Controls
Biological Safety/OESO/DUHS 2/2016
Side 1

Is Patient Still Considered Infectious?(2)

Yes

No

Can Visit Be Delayed?

Yes

Reschedule

No

Patient with Suspected or Known TB?

Yes

No

See Other Side

Does Patient Exhibit Signs and Symptoms of TB?

Yes

No

Can Patient Wear Surgical Mask During Entire Visit?

Yes

No

Use General TB Precautions (4)

Use Full TB Precautions (3)

Can Patient Wear Surgical Mask During Entire Visit?

Yes

No

Use General TB Precautions (4)

Use Full TB Precautions (3)

Full TB Precautions in addition to General TB Precautions:

- The employee wears respiratory protection (a N95 respirator that they have been fit-tested for or a PAPR unit).
- Patient is placed in All room or into exam room with portable HEPA unit (follow instructions posted on unit for use and for ventilation after the patient vacates). Patient may remove surgical mask for exam/procedure.
- Place an All sign on the door during patient visit and until the room has been ventilated for 30 minutes.
- High-hazard procedures (e.g., sputum collection/induction, bronchoscopy) must be performed in a negative pressure All room (bronchoscopy suites, Advanced Therapeutics Clinic, or designated inpatient hospital rooms).

General TB Precautions:

- Schedule visit when the patient will not have to wait, and when the fewest other patients are scheduled.
- Instruct the patient to wear a surgical mask when entering the building and keep it on during the entire visit. Respiratory protection is not needed for the employee.
- Place the patient directly into an exam room and close the door.
- Routine procedures are used to clean the exam rooms vacated by TB patients wearing a surgical mask.

(1) Fit-Tested Employees or PAPRs and Airborne Infection Isolation (All) Rooms or portable HEPAs available. (All clinics in Duke Clinic)
(2) Noninfectious is: 2 negative sputum smears (collected at least 8 hours apart, collected after 14 days of treatment, and the last positive collected at least 7 days before the 2 negative sputum smears); patient is clinically improving; and is on drug therapy for 2 weeks.
(3) In an emergency with an unmasked patient a N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.
(4) If collecting sputum “Use Full TB Precautions”.

Appendix B
Clinic Visits from TB Patients – Hierarchy of Controls
Biological Safety/OESO/DUHS 2/2016
Side 2

Can Patient Be Referred to the Health Department, an Equipped Clinic or the ED?
Yes
No

Can the Patient Still Be Considered Infectious?
Yes
No

Is the Patient in the Clinic?
Yes
No

Can Visit Be Delayed?
Yes
No

Place Surgical Mask or Other Barrier on Patient ASAP and Remove Patient from Clinic (3).
Use General TB Precautions (4)

Place Surgical Mask on Patient ASAP and Transfer Patient
Can Patient Wear Surgical Mask During Entire Visit?
Yes
No

Can Patient be Referred to an Equipped Clinic?
Yes
No

Refer Patient to ED and Instruct Patient to Wear Surgical Mask
Refer Patient and Instruct Patient to Wear Surgical Mask

General TB Precautions (all off-site clinics):
♦ Schedule visit when the patient will not have to wait, and when the fewest other patients are scheduled.
♦ Instruct the patient to wear a surgical mask when entering the building and keep it on during the entire visit. Respiratory protection is not needed for the employee.
♦ Place the patient directly into an exam room and close the door.
♦ Routine procedures are used to clean the exam rooms vacated by TB patients wearing a surgical mask.

Appendix B

(1) Fit-Tested Employees or PAPRs and All rooms or portable HEPA units available. (All clinics in Duke Clinic)
(2) Noninfectious is: 2 negative sputum smears (collected at least 8 hours apart, collected after 14 days of treatment, and the last positive collected at least 7 days before the 2 negative sputum smears); patient is clinically improving; and is on drug therapy for 2 weeks.
(3) In an emergency with an unmasked patient a N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.
(4) Sputum is collected using “Full TB Precautions” at an Equipped Clinic.
TB ECP Appendix C:

Annual TB Surveillance Groups – February 2016

- **Personnel** assigned to work in the following *high risk areas* (including nurses, PRMs, Social Workers, PAs, and NPs, clerical employees, and EVS employees):
  - Emergency Department
  - Urgent Care Clinics (in Durham and Wake Counties)
  - Life Flight (all EMS transport personnel)
  - Bronchoscopy (Adult and Pediatrics) – Includes Clinic 2H (outpatient)
  - Infectious Disease Clinics – Adult and Peds (CHC)
  - All Pulmonary Clinics - 2F/2G, off-site, and Peds (CHC)
  - Advanced Therapeutics Clinic-2A (non-Oncology infusion)

- **Housestaff** assigned to work in the following specialty groups/programs:
  - Emergency Department (part of Surgery/Trauma)
  - Infectious Diseases (Adult and Peds)
  - Pulmonary Medicine (Adult and Peds)
  - Internal Medicine
  - Combined Medicine and Pediatrics
  - Psychiatry

- **MD Faculty** working in the following specialty groups/programs:
  - Emergency Department (part of Surgery/Trauma)
  - Infectious Diseases (Adult and Peds)
  - Pulmonary Medicine (Adult and Peds)
  - Hospitalists (Adult and Peds)

- **Hospital Radiology** patient-care providers in Diagnostic X-Ray, Peds Diagnostic X-Ray, and CT (i.e., technologists, clinical tech. assistants)

- **All Radiology RNs**

- **Respiratory Care and Pulm Func Lab** patient-care providers and equipment handlers

- **Clinical Microbiology Lab** employees that work with AFB (supervisor will designate)

- **All Autopsy** personnel (including MDs)

- **Surgical Pathology** personnel (employees who perform frozen sections on specimens suspicious of TB)

- **Cytology** staff assisting with fine needle aspirates in Bronchoscopy (supervisor will designate)

- **E & O** employees that work in *high risk areas* of the hospital, clinic, GHRB, and CARL building (supervisor will designate)

- **Vascular Access Team** (formerly IV Team)

- **Neurodiagnostics Techs**

- **Patient Advocates**

- **Interpreters** (International Patient Center)

- **Pastoral Care Staff**

- **Inpatient Phlebotomists** (CLSS and Peds)

- **Peds Clinical Lab Techs** (only those performing inpatient phlebotomy)

- **Laboratory staff** that assist with bone marrow biopsies (supervisor will designate)

- **Employees** that work with non-human primates
Appendix D *All Rooms for Known and Suspect TB Patients – February 2016*

**Designated TB 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 by Employee Health for the N95 respirator mask on these nursing units.

<table>
<thead>
<tr>
<th>Duke Hospital</th>
<th>DMP 6E (MICU)</th>
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<tbody>
<tr>
<td>4332</td>
<td>7822 8101</td>
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<tr>
<td>5101 (Peds)</td>
<td>7831 8332</td>
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<td>5131 (Peds)</td>
<td>7833 12</td>
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<td>7834 16</td>
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</table>

**Back-up TB 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 by Employee Health for the N95 respirator mask must use the PAPR for respiratory protection.

<table>
<thead>
<tr>
<th>Duke Hospital</th>
<th>DMP Rooms</th>
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<tbody>
<tr>
<td>2101 (Med/Surg)</td>
<td>6W 9 – 16  (SICU)</td>
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<td>2332 (Med/Surg)</td>
<td>7E 9 – 16  (CT SD)</td>
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<tr>
<td>3101 (CT SD)</td>
<td>7W 13 – 20 (CT ICU)</td>
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<td>3332 (CT SD)</td>
<td>8E 9 – 16  (Neuro ICU)</td>
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<td>4101 (Neuro SD)</td>
<td>8W 13 – 20 (Neuro SD)</td>
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<td>5610 (PICU)</td>
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<td>6101 (Ortho)</td>
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<td>6332 (Special Svcs)</td>
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<td>7101 (Heart)</td>
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<td>7201 (CCU)</td>
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<tr>
<td>7216 (CCU)</td>
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<tr>
<td>7332 (Heart)</td>
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<td>7732 (Peds &amp; OB)</td>
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<tr>
<td>9101 (Hemonc)</td>
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<td>9201 (BMTX)</td>
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<td>9332 (Onc)</td>
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<td>BUILDING</td>
<td>FLOOR / DEPT.</td>
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<tr>
<td>DMP</td>
<td>1 / Bronchoscopy</td>
</tr>
<tr>
<td>Duke Hospital</td>
<td>Emergency Department</td>
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<td>Duke Hospital</td>
<td>PACU</td>
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<td>DMP</td>
<td>PACU</td>
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<tr>
<td>Children’s Health Center</td>
<td>3 / Peds Bronchoscopy</td>
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<tr>
<td>Duke Clinic</td>
<td>2 / Clinic 2A, Adv. Th. Ctr.</td>
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<tr>
<td>Duke Clinic</td>
<td>2 / Clinic 2H, GI-Bronch. Suite</td>
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<tr>
<td>Duke Clinic</td>
<td>3 / Autopsy</td>
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<tr>
<td>CARL</td>
<td>1 / Clinical Microbiology Laboratory</td>
</tr>
<tr>
<td>Duke Asthma, Allergy, and Airway Center</td>
<td>1821 Hillandale Rd.</td>
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Appendix E

Airborne Infection Isolation Room Instructions

1. **PERFORM THE TISSUE TEST DAILY** by holding a small piece of tissue in front of the door just 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 “Daily Tissue Test Log for Negative Air Pressure”, below.

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**
   ♦ 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 3 TYPES OF RESPIRATORY PROTECTION IN THE ANTEROOM FOR USE BY EMPLOYEES AND VISITORS:**
   ♦ KC Technol N95 Respirator Masks (Orange Duck Bill Respirator Mask) – SAP #14174.
   ♦ 3M N95 Respirator Masks (Teal Respirator Mask) – SAP #14173 (regular) and #26378 (small).
   ♦ SafetyTech FlexAir Powered Air Purifying Respirators (PAPRs) for those who are not fit-tested with the N95:
     • PAPRs are plugged into the charger when not in use.
     • PAPRs can be ordered from Equipment Distribution through Maestro.
     ✓ *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 681-2072, 24/7).*
     • Use Only Safety Tech PAPR Head Covers – SAP #330895 (Remove blue fil before use.)

6. **WEAR APPROVED RESPIRATORY PROTECTION TO ENTER PATIENT ROOM**
   ♦ An annual fit-test by EOHW is required to use an N95 respirator mask, otherwise use a PAPR.
   ♦ Perform a user “seal-check” each time you wear an N95 respirator mask.

7. **THE PATIENT SHOULD WEAR A SURGICAL MASK IF TRANSPORT OUTSIDE OF THE ROOM IS ESSENTIAL**
   ♦ Patients on Airborne Infection Isolation are not to leave their room unless medically necessary or Infection Prevention has given approval.

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: 684-5457 or 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. **BEFORE DISCONTINUING ISOLATION FOR A TB PATIENT NOTIFY INFECTION PREVENTION**

11. **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.
    ♦ Respiratory protection must be worn to enter the room before this time is up and all the doors must remain closed.
DUH AIRBORNE INFECTION ISOLATION (AII) ROOM
DAILY TISSUE TEST LOG FOR NEGATIVE AIR PRESSURE

Room: ____________     Unit: ____________

<table>
<thead>
<tr>
<th>Date</th>
<th>Negative Air Pressure Validated</th>
<th>Nursing Initials</th>
<th>Date</th>
<th>Negative Air Pressure Validated</th>
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- Notify E&O immediately if room fails negative pressure check at: 684-3232
  - Ask patient to wear surgical mask until the patient is transferred to another AII room, a portable HEPA is placed in the room, or the negative pressure is restored by E&O.
- File this form in *Tissue Test Notebook* kept on the unit when All precautions are discontinued.
Health care workers that enter rooms with patients on Airborne Infection Isolation in the following **areas** (including nurses, PRMs, Social Workers, PAs, NPs, and EVS workers):
- 4300
- 5100
- 5600 (PICU RNs Only)
- 7800
- 8100
- 8300
- DMP 6E
- Emergency Department (including unit coordinators)
- Urgent Care Clinics (in Durham and Wake Counties)
- 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 and Pediatrics) including Clinic 2H (outpatient)
- Oncology Treatment Center – Cancer Center (risk to aerosolized BCG)
- 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
- Psychiatry

**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

**Hospital Radiology** patient-care providers in Diagnostic X-Ray, Peds Diagnostic X-Ray, and CT (i.e., technologists, clinical tech. assistants)

**All Radiology RNs**

**Clinical Microbiology employees working with AFB** (supervisor will designate)

**Laboratory staff** that assist with bone marrow biopsies (supervisor will designate)

**Surgical 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** (CLSS and Peds)
**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
- ISRP Float Pool Patient Care Providers
- 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)
- **Low-risk Radiology** departments (i.e., technologists, clinical tech. assistants):
  - Clinic-Based Diagnostic X-Ray, Clinic-Based CT, Mammography, Neurology Intervention, Ortho, GI, GU, Vascular Intervention, Pet Scan, Nuclear Med, Ultrasound & Fetal Diagnostic Center
  - Note: MRI Techs are not classified as needing respiratory protection
Wear It Right

3M™ Respirators

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 pinching in an upward and 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 loss of effective respirator performance.

POSITIVE PRESSURE AT CHECK

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 use in a requiring respirator use.

REMOVAL:

1. Without touching the respirator, slowly lift the bottom strap from around your neck 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.

WARNING

This respirator helps protect against certain particulate contaminants, but does not eliminate exposure to oral 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.

3M Health Care
3M Center, Building 275-4W-02
St. Paul, MN 55144-0000
U.S.A.
1 800 228-3957
www.3m.com/healthcare

3M Canada
Post Office Box 5757
London, Ontario N6A 4T1
Canada
1 800 563-2521

Outside of USA, please contact your 3M Representative

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70-2539-057-1
Kimberly-Clark

Proper Wearing of Kimberly-Clark* Tecnol*
PFR95* N95 Particulate Filter Respirators and Surgical Masks

To ensure your PFR95 N95 Particulate Filter Respirator provides the intended level of protection, it is important that the respirator is applied properly and that a Fit Check is performed EACH AND EVERY TIME you wear it.

NOTE: When using a HAZARDSHIELD® PFR95 N95 Particulate Filter Respirator, the orange side MUST be worn facing outward and upward in order to provide fluid resistance protection.

Directions for Proper Fitting:
Properly donning your PFR95 N95 Particulate Filter Respirator may feel a little awkward at first, but it will become easier with repeated applications. Please use the instructions to the left when applying the respirator.

Tips for Achieving a Good Fit:
If you have a problem successfully Fitting your respirator, try the following tips:
1. Use a mirror while adjusting the respirator.
2. Ask someone to look for hair or earrings that might be caught in the seal.
3. Make sure the headbands are positioned properly. It is especially important that the top headband is on the crown of your head, as it is designed to hold the bottom of the respirator snug against your chin.

NOTE: If using these tips, you are still unable to successfully fit check your respirator, try your supervisor or respiratory protection coordinator.

DIRECTIONS FOR FIT CHECKING:
It is important to fit check the respirator every time you wear it.

Prebreath and exhale several times. The respirator should collapse slightly when you inhale and expand when you exhale. You should not feel any air leaking between your face and the respirator.

If the respirator does not collapse and expand OR if air is leaking out between your face and the respirator, then you have NOT achieved a good seal fit. Adjust the respirator and the binding is rechecked and you are able to successfully fit check your respirator.

Kimberly-Clark
Protection. For life.
Appendix H – 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/s 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. In Duke Hospital OR use one portable HEPA per suite and in the DMP OR use two portable HEPA/s per suite. The 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).

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 respirator masks (or a PAPR if that employee 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 mask provides acceptable temporary protection whether the employee is fit-tested or not. In cases where TB is suspected before the surgery, every effort will be made to identify those staff that will be working 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 Section VIII E) or remain in the Operating Room with the portable HEPA filter still running.

7) The following ICU level isolation rooms are on a designated TB unit: DMP 6 East (MICU) rooms 9 – 16. If a patient requires AII, attempts must be made to first place them in one of these rooms. If these rooms are already occupied by patients on AII, or if medically
the patient requires the specialized care of one of the other intensive care units then one of the following isolation rooms may be used: DMP 6 West (SICU) rooms 9 – 16, DMP 7 West (CT ICU) rooms 13 – 20, DMP 8 East (Neuro ICU) rooms 9 – 16, 5610 (pediatrics only), 7201, and 7216. Patients on All have priority for these rooms.

8) In cases of known multi-drug resistant tuberculosis that require surgery, contact Biological Safety (684-8822) for coordination of additional engineering controls to be implemented by the Engineering and Operations HVAC division. Also contact EOHW 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 I

Management of Known and Suspected Tuberculosis (TB) Patients in the Cardiac Catheterization and Electrophysiology Laboratories

1) Because the Cardiac Catheterization Laboratory (Cath Lab) and the Electrophysiology Laboratory (EP Lab) lack an Airborne Infection Isolation procedure room, 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.

2) 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 Equipment Request Portal:

http://vmw-cetmsweb.duhs.duke.edu/webrequest/wrMaster.aspx?p=35&d=TTHzGY5mxmI=&s=Gp8S3R/Sm0SDahMaGUF/eg==&logout

or through Maestro. (For immediate needs or emergent situations call the Equipment Distribution Hotline at 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 a powered air purifying respirators (PAPRs) if the employee works outside the sterile field). Since the Cath Lab and EP Lab are areas of low risk for TB transmission, routine fit-testing for the N95 respirator is not required. In cases that 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 be performed. The N95 respirator mask provides acceptable temporary protection whether the employee is fit-tested or not. 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 provide them with N95 respirator fit-testing prior to the procedure.

6) During transport to and from the Cath Lab 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”