

TUBERCULOSIS EXPOSURE CONTROL PLAN

(First approved July, 1995)

SCOPE: *THIS PLAN APPLIES TO DUKE UNIVERSITY HEALTH SYSTEM. IN THIS DOCUMENT THESE ENTITIES WILL BE COLLECTIVELY REFERRED TO AS "DUKE".*

Preface

The primary purpose of this document is to detail a Tuberculosis Exposure Control Plan for Duke. This Plan was approved by the Duke University Hospital Infection Control Committee and Duke University Safety Committee in July 1995, with revisions approved June 1996, July 1997, July 1998, November 2000, December 2001, March 2003, February 2004, February 2005, February 2006, March 2007, March 2008, March 2009, February 2010, February 2011, February 2012, March 2013, February 2014, February 2015, February 2016, February 2017, March 2018, February 2019, April 2019, April 2021, September 2021, and March 2022. In July 2023, this plan was expanded to cover the entire Duke University Health System, including Duke Regional and Raleigh Hospitals, Duke Health Integrated Practice, Duke Primary Care, and Clinical labs.

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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.

In the following plan, “Duke” refers to the entire Duke University Health System, including Duke University Hospital (DUH), Duke Regional Hospital (DRH), Duke Raleigh Hospital (DRaH), Duke Primary Care (DPC), Duke Health Integrated Practice (DHIP), and Clinical Laboratories. Additionally, “Infection Control Committee” refers to the committee of the hospital that reviews Infection Prevention information. These committees are called:

- DUH: Hospital Infection Control Committee (HICC)
- DRH: Infection Prevention and Anti-Microbial Stewardship Committee (IPASC)
- DRaH: Infection Prevention and Control Committee (IPCC)

II. OVERVIEW OF INFECTION PREVENTION MEASURES

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

III. RISK ASSESSMENT

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

- B. **EOHW** will provide reports to the Infection Control Committee specific to each entity quarterly that include, along with appropriate demographic information:
- a) The number of hospital employees with known occupational exposure to TB,
 - b) The number of employees who had a TB assessment following occupational exposure and their baseline status,
 - c) The number of employees who converted their TB status after a known exposure to a patient with active tuberculosis, and
 - d) The number of employees with exposure who were lost to follow-up.
- C. **EOHW** will maintain records on all TB assessments done on new (baseline testing) and current employees (post-exposure TB testing). In an annual written report to Biological Safety for the TB Annual Report, EOHW will summarize, including appropriate demographic information, the following data:
- a) Results of TB evaluations on new placements.
 - b) Results of TB evaluations on healthcare workers involved in known potential exposures.
- D. **Biological Safety** will annually summarize and present the following to HICC and the Duke University Safety Committee (DUSC) for DUH, while **Infection Prevention** presents to IPASC and IPCC for DRH and DRaH, respectively:
- a) Duke hospital employee compliance to EOHW and OESO TB requirements,
 - b) The number of culture confirmed TB cases at Duke,
 - c) The number of employees investigated in potential TB exposure cases and the number of conversions associated.
 - a) Include any evidence of trends or unusual circumstances.
 - b) Include recommendations for preventing future potential exposures, if any.
 - d) The compliance rate of new healthcare worker TB evaluations with baseline tuberculin skin testing (TST) and respirator requirements of medical clearance, fit testing, and training
 - e) The total number of days of isolation for:
 - a) Tuberculosis
 - b) Suspected tuberculosis
- E. **Biological Safety** will assess the potential of occupational exposure to TB for all Duke healthcare workers. Since this encompasses multiple sites and types of services, specific areas or functional groups within the setting have separate risk classifications. Each employee will be assigned at least one of the following exposure determinations:

- 1) Airborne Pathogens
 - a) 0 – Not likely or anticipated exposure to TB Complex
 - b) 1 – Work assignment for all or part of the employee’s scheduled work time in areas where there is a low risk of exposure to TB aerosols (e.g., patient care areas/buildings)
 - c) 2 – Work assignment includes the potential use of an N95 respirator (See Section VIII I)
 - d) 3 – Work assignment includes the potential use of a Powered Air-Purifying Respirator (PAPR) (See Section VIII I).
 - e) 4 – Work assignment is located in the Clinical Microbiology Laboratory (CMB) acid-fast bacillus (AFB) section.
 - f) 5 – Not in use
 - g) 6 – Not in use
 - h) 7 – Not in use
 - i) 8 – For employees with a latent TB infection (LTBI), requiring a “Special EOHW Review” of the annual TB Questionnaire

IV. RESPONSIBILITIES

A. Employees

- 1) All employees with exposure determinations of Airborne Pathogens 1– 4, and 8 are required to complete online educational programs related to tuberculosis control and comply with tuberculosis control policies outlined in this plan.
- 2) Employees with a designation of Airborne Pathogens 2 or 3 must comply with the requirements of the Respiratory Protection Program Policy for TB (see Section VIII I).
- 3) Employees will conduct a “user seal-check” prior to each use of the N95 respirator.
- 4) 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 Duke’s tuberculosis policies and compliance with OESO tuberculosis educational programs on their yearly performance evaluation.
- 2) Enforce the requirements of this plan.
- 3) Assist OESO/EOHW in the scheduling of any training, fit-testing, medical evaluations, or any other activity relating to compliance of this program.

- 4) Provide OESO with employee's job duties and physical location to help determine the risk
- 5) Assist OESO with collecting names of potential exposed employees during a TB exposure investigation.
- 6) Assure that appropriate respiratory protection is available.

C. Infection Control Committees

- 1) Each hospital has its own Infection Control Committee. As follows, they are:
 - a) DUH: Hospital Infection Control Committee (HICC)
 - b) DRH: Infection Prevention and Anti-Microbial Stewardship Committee (IPASC)
 - c) DRaH: Infection Prevention and Control Committee (IPCC) and Antimicrobial Stewardship Team (AST)
- 2) The Infection Control Committee receives reports annually from OESO/IP and at least twice a year or more frequently from EOHW that include any TB activity. Thereafter the HICC will report these findings to the Executive Committee of the Medical Staff.
- 3) The Chair will review and then arbitrate any controversies or disagreements over proper isolation of individual patients with known or suspected tuberculosis. The authority for this activity is outlined in the bylaws of the Duke Hospital and Clinics Medical Staff. These bylaws specifically state the Chair has the responsibility and authority to mandate specific isolation should disagreement occur between Duke Physicians and personnel from Infection Prevention and Hospital Epidemiology (IPHE).
- 4) The Chair will be notified of any investigations of tuberculosis exposure of employees and students undertaken by Biological Safety/IP and EOHW by report at the committee.
- 5) The Infection Control Committees and the DUSC will review the Hospital TB Exposure Control Plan at least annually.

D. Infection Prevention and Hospital Epidemiology (IPHE)

- 1) Assure compliance with Duke policies as to the initiation and discontinuation of Airborne Infection Isolation (All) of all patients with known or suspected infectious tuberculosis. See Section VIII of this document, "Management of Patients with Known or Suspected Tuberculosis" for details on the specific safety precautions to be used with

All. **On-call advice is available 24 hours a day, 7 days a week by calling Infection Prevention at:**

- a) **Duke University Hospital (DUH): 919-684-5457 or pager 919-970-9721**
 - b) **Duke Regional Hospital (DRH): 919-470-7171 or pager 7171 (available 0800-1700 daily)**
 - c) **Duke Raleigh Hospital (DRaH):919-954-3166 or pager 919-206-3311**
- 2) Participate (in conjunction with OESO and EOHW) in the orientation and continuing education of all new and current employees concerning tuberculosis control policies.
 - 3) In conjunction with OESO and EOHW review the tuberculosis exposure control plan annually.
 - 4) Report or assist in reporting all cases of known or suspected tuberculosis to the health department in the patient's county of residence. In turn, the health department will notify the NC Department of Health and Human Services (Appendix A).
 - 5) Notify Biological Safety of all patients placed in isolation for confirmed infectious tuberculosis, all positive AFB smears in patients with suspected infectious tuberculosis, and all TB Complex positive specimens/cultures.

E. Biological Safety/OESO at DUH, IP/EOHW at DRH, DRaH

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

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

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

F. Employee Occupational Health and Wellness (EOHW)

- 1) Provide new employees who need a medical placement health review with TB screening as defined in Section V to include:
 - a) Prior TB history and any previous therapy for tuberculosis.
 - b) Prior TST or IGRA (Interferon Gamma Releasing Assay) results (to include dates of the most recent negative or positive results).
 - c) Prior therapy for active or latent tuberculosis including dates, types of treatment and results of prior chest radiographs.
- 2) Follow up with all employees potentially exposed to TB according to the procedure in Section VI
- 3) Evaluate all employees identified earlier in Section F.1 with suspected or known active tuberculosis according to CDC guidelines. 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.

- 4) Follow-up of employees with non-occupational elevated risk for TB infection that have been identified through an annual questionnaire that is part of the annual online TB training.
- 5) Implement medical clearance for employees subject to the Respiratory Protection Program Policy for TB (Section VIII.I).

G. Duke Student Health Service

- 1) Since Duke students have the potential to be exposed to TB through hospital and/or clinic rotations, all incoming Duke students will be screened through a TB Screening Questionnaire. Students identified as high risk will be required to submit a TST or IGRA within 6 months prior to matriculation.
- 2) All Duke medical students and other allied health students will have tuberculosis testing within 6 months prior to matriculation.
- 3) Duke Student Health only performs IGRA blood tests and does not place TSTs for baseline evaluation. TSTs will be placed for exposure assessments.
- 4) Students with a history of a positive TB test will be required to submit a symptom monitoring checklist, a chest x-ray done in the US in the last 2 years, and a TB Clearance Statement signed by a provider, if indicated. If the student provides documentation of treatment for active or latent TB, no chest x-ray is required.
- 5) All students who have a documented or suspected exposure to a patient with infectious tuberculosis will be evaluated at the Student Health Center using the same criteria as for Duke Employees (see Section VI).
- 6) Students have 7 days following notification of the need for post-exposure tuberculin testing in which to record a current TST result with Duke Student Health. Any student who has not had tuberculin testing results recorded in Student Health within two weeks of the notification will be restricted from clinical rotations by their respective Health Science Program. A second test will be required approximately 8 – 10 weeks after exposure.
- 7) Students who perform patient care activities and travel to countries or areas within the U.S. designated by CDC/WHO as high hazard/high burden for TB must have a recorded tuberculin test result with Duke Student Health within a time frame of greater than 8 – 10 weeks and not more than six months after returning to Durham. Noncompliant students will be restricted from clinical rotations by their respective Health Science

Program. Programs will need to inform Student Health of any student travel that meets the description above.

- 8) Any student with active tuberculosis will be restricted from the classroom/patient care/campus study and living areas until treated and evaluated by the same criteria used to manage Duke employees.

H. The Clinical Microbiology Laboratory (CMB)

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

CMB will call the patient's physician and Infection Prevention (919-684-5457 or 919-970-9721; DRH 919-470-7171; DRaH 919-206-3311) with:

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

I. Anatomic Pathology

- 1) The Department of Pathology (including Autopsy, Cytology and Surgical Pathology) will notify the patient's provider either via phone, writing or pathology report when specimens, tissues or organs are found on pathological examination to exhibit findings consistent with an infectious form of tuberculosis. Whenever possible samples suspicious for

tuberculosis infection will be sent to the Clinical Microbiology Laboratory for AFB culture to confirm disease and for epidemiological investigations by Biological Safety and the North Carolina public health system.

- 2) The Autopsy Department will notify Infection Prevention when gross or microscopic examination of a patient without a known infection is positive for any form of tuberculosis.
- 4) The Surgical Pathology Department will notify the patient's provider when they encounter any necrotizing caseous granulomatous lesion with or without a cavitory component which has findings consistent with an infectious form of tuberculosis. In the Surgical Pathology Department, procedures that have the potential of producing aerosols on specimens from patients with known or suspected infection including all lung specimens are performed using appropriate biosafety precautions for the specific process/procedure in accordance with CDC/NIH guidelines.
- 5) The Cytopathology Unit will notify Infection Prevention of any AFB smear-positive results.

V. TUBERCULOSIS SCREENING AND TREATMENT

A. Tuberculosis screening is required for new employees working in patient care areas or buildings including new unpaid workers (e.g., volunteers, providers, and observers).

- 1) Unpaid workers who test positive on the TST are referred to their primary care physician or Health Department for further assessment.

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

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

D. Student Health requires TB testing on all Duke Health Science students. TB testing is also required within 6 months for all students volunteering and those newly matriculated students identified as high risk per the TB Screening Questionnaire.

- 1) Additionally, all healthcare contract workers must comply with Duke Policy through their respective agencies prior to job placement.

- E. EOHW will provide annual summaries of tuberculosis screening with documentation of any TB conversions to Biological Safety/OESO.
- F. TB testing will be performed on all new employees working in patient care areas or buildings unless they have one of the following conditions:
- 1) Documentation of a prior TST reaction interpreted as positive according to CDC guidelines (see section F) or positive IGRA (interferon gamma release assay). The employee must provide documentation of a previous positive test or the employee will be tested again by EOHW.
 - 2) Documentation of prior treatment for tuberculosis infection or disease.
 - 3) Documented as currently receiving anti-tuberculosis therapy.
 - 4) Documented negative test within the last year.
 - 5) Employees with documentation of allergy (i.e., immediate hypersensitivity) to TST reagents will receive an IGRA in lieu of a TST.
- G. Pregnancy is not a contraindication for tuberculin skin testing. The same guidelines used for non-pregnant employees will be utilized to test and evaluate pregnant employees with two exceptions:
- 1) Pregnant employees infected with TB Complex will be informed of the possibility that infection can progress more rapidly during pregnancy.
 - 2) Pregnant employees who meet current guidelines for prophylactic therapy or treatment of active disease will be handled on an individual basis in conjunction with their primary physician. [Note: both Isoniazid (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].
- H. A standard TST will employ 0.1 mL (5 units) of tuberculin and will be assessed 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 assessed by other licensed HCWs (i.e., MD, RN, PA, or NP). Student Health will assess all TSTs for students.
- 1) Two step TST will be done on individuals in the following groups (unless employee provides documented 2 step TST or IGRA within the previous twelve months).
 - 55 years of age or older

- Coming from an area with a high prevalence of TB [according to current data from the World Health Organization](#) (WHO) with a documented prior negative TST.
 - A history of BCG with a documented prior negative TST.
 - Equivocal prior test results.
- 2) An IGRA will be done on individuals in the following groups (unless employee provides documented 2 step TST or IGRA within the previous twelve months):
- Coming from an area with a high prevalence of TB according to current data from the WHO, without a documented prior negative TST.
 - A history of BCG, without a documented negative TST.
- I. All TST reactions meeting the following criteria will be classified as positive:
- **Induration of 5 or more millimeters if:**
 - a) People living with HIV
 - b) Recent contact of a patient with infectious TB disease
 - c) Their screening X-ray findings (such as fibrotic changes) suggestive of previous TB disease
 - d) Individuals with organ transplants
 - e) Other immunosuppressed people (eg., including those on prolonged therapy with corticosteroids equivalent to/ greater than 15 mg per day of prednisone or taking tumor necrosis factor-alpha (TNF- α) antagonists (such as etanercept (Enbrel®), infliximab (Remicase®), adalimumab (Humira®) or anakinra (Kineret™)).
 - **Induration of 10 or more millimeters if:**
 - a) People born in countries where TB disease is common, including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB (includes any country other than the United States, Canada, Australia, New Zealand, or a country in western or northern Europe).
 - b) People who abuse drugs
 - c) Mycobacteriology laboratory workers
 - d) People who live or work in high-risk congregate settings (e.g., nursing homes, homeless shelters, or correctional facilities)
 - e) People with certain medical conditions that place them at high risk for TB (e.g., silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions)
 - f) People with a low body weight (<90% of ideal body weight)

- **Induration of 15 or more millimeters** if there are no known risk factors for TB (see sections above).

J. Employees with positive tuberculosis testing:

- 1) Employees with LTBI and employees who have LTBI and who have completed a course of preventive therapy in accordance with CDC recommendations 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).
- 3) If an employee is a new converter:
 - 1) All employees with documented recent TST or IGRA conversion will be counseled by EOHW and have the following tests:
 - a) 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.
 - b) Chest x-ray
 - c) HIV testing
 - 4) Preventive therapy will be recommended for all recent tuberculin or IGRA converters consistent with current recommendations of the CDC and the Advisory Council for the Elimination of Tuberculosis (ACET).
 - 5) If drug prophylaxis is not taken for new LTBI, a chest x-ray is repeated after 18-24 months. (If conversion occurred within the previous 2 years and drug prophylaxis was not taken, a current CXR is obtained).

K. Active Tuberculosis:

- 1) Anti-tuberculous therapy based on current CDC recommendations will be advised for all employees with active tuberculosis. Treatment is with the employee's personal physician or with the health department in the employee's county of residence. Employees will be relieved from work activities until EOHW authorizes their return. The local health department will be notified and consulted.
- 2) All employees with active tuberculosis will be informed of the risk of disease among household contacts. In such instances, follow-up and treatment of household contacts will be the responsibility of the local health department.

VI. EXPOSURE INVESTIGATION

An exposure will be defined as:

1. Spending time in an enclosed space with a patient with smear positive, pulmonary, infectious tuberculosis where All precautions were not utilized.
 2. Exposure to TB aerosols (both smear negative and positive) during certain procedures (e.g., bronchoscopy, laboratory accidents, irrigation of surgical sites or wounds, extubation, suctioning, sectioning frozen samples, HVAC repair, etc.).
 - a) Smear status to determine infectiousness is smear results collected on three respiratory specimens prior to initiation of anti-tuberculosis medication treatment.
 - b) Consultation with the Health Department TB Nurse in the patient's county of residence to determine the scope of the investigation will be pursued as needed.
- A. At DUH, Infection Prevention (IP) will notify OESO when a patient with infectious TB has been newly diagnosed or admitted with known TB to the hospital or seen in the clinics. It will be the responsibility of EOHW and OESO to follow up on possible employee exposures. At DRH and DRaH, IP will work with EOHW on investigations.
- B. Records of patients will be reviewed to collect names of potentially exposed employees and estimate cumulative potential exposure time for these employees. OESO (DUH) or IP (DRH and DRaH) 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 (DUH) or IP (DRH and DRaH) 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 initially on staff that were in direct contact with the infectious patient and then will follow the concentric circle method. Any conversions within this first group will result in expanded follow-up. 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, including the duration of the exposure, other factors such as PPE, and the presence or absence of signs and/or symptoms of active tuberculosis in the source patient.
- D. Surgical Pathology/Autopsy employees who are directly involved with the handling and/or preparation of surgical specimens confirmed as positive for TB complex will be included in TB exposure investigations when proper 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 TB in the exposed employee, prior TB status of the employee, and the subsequent risk of TB infection and/or disease in the employee. Once notified, it is expected that

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

- F. In addition, OESO (DUH), IP (DRH and DRaH) or EOHW will notify outside contractors if any of their employees have been exposed to tuberculosis. It will be the responsibility of these outside contractors to contact such exposed individuals and arrange for their appropriate evaluation and follow-up.
- G. Exposed employees will have their TB status established following a significant exposure. If the employee has not had a TST placed within the last three months prior to the exposure, a baseline TST will be placed at that time. When such tests are negative, a follow-up TST will be repeated 8-10 weeks post-exposure. If employee has a history of BCG or life in an area endemic for TB then IGRA can be used for testing.
- H. In all instances of nosocomial transmission of TB 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 sponsored by DUHS and including an EOHW pre-travel health review in a country that has a high prevalence of TB according to current data from the [World Health Organization](#) the employee is expected to undergo evaluation by EOHW when returning to work at Duke.

VII. EDUCATION

- A. OESO is responsible for education of staff concerning TB control policies, procedures and their implementation.
- 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 TB 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, and 8:
 - 1) Basic concepts of the transmission, pathogenesis and diagnosis of TB (including the difference between TB infection and active disease due to TB, potential signs and symptoms of TB and the possibility of late reactivation of asymptomatic TB infection).

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

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

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

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

1. Signs and Symptoms of Active Pulmonary TB:

- Persistent cough (> 3 weeks)
- Hemoptysis (bloody sputum)
- Chills and fever
- Night sweats
- Unexplained weight loss
- Chest X-ray changes suggestive of TB
- Chest pain
- No appetite
- Weakness or fatigue

2. Groups at High Risk for TB:

- Close contacts of active TB cases
- Individuals born in countries with high TB rates (refer to [the World Health Organization's website](#) for updated information).
- Persons with alcohol use disorder
- Persons who inject drugs
- Residents and employees of high-risk congregate settings (e.g., long-term care facilities, homeless shelters, or prisons)

- Persons with certain medical conditions that increase the risk of developing clinical tuberculosis once tuberculosis infection has occurred:
 - HIV infection (due to immunosuppression)
 - Silicosis
 - Abnormal chest radiograph showing fibrotic lesions
 - Diabetes mellitus
 - Prolonged corticosteroid therapy
 - Immunosuppressive therapy
 - Hematologic and reticula endothelial diseases
 - End-stage renal disease
 - Intestinal bypass
 - Post-gastrectomy
 - Chronic malabsorption syndromes
 - Head, neck, and lung cancers
 - Being 10% or more below the ideal body weight
3. Diagnosis of TB should be considered in any patient presenting with any signs and symptoms of active TB. Also, if a patient presents with any of these signs and symptoms and belongs to one or more of the groups at high risk for TB, then suspicion for active TB should be raised.
- Place the patient on All immediately; details follow (see VIII.D below).
 - Appropriate diagnostic studies should be conducted. These may include:
 - TST or IGRA
 - Three consecutive sputum specimens collected at least eight hours apart, one of which should be an early morning specimen. These sputum specimens are used to perform smears and cultures. The three smear results are used to determine infectiousness.
 - In smear positive sputum specimens a polymerase chain reaction (PCR) test should also be performed. A positive PCR test is confirmatory for TB complex. For inpatient testing, a negative PCR test should be repeated once on a second smear positive sputum specimen.
 - Chest radiography. In patients with normal immune systems the chest x-ray is often the most valuable tool used to raise suspicion for TB. Persons with impaired immune systems often do not have chest x-rays suggestive of TB even though they may have the disease.
 - In selected instances, bronchoscopy, sputum induction by nebulizer, nasogastric aspirations (for pediatric patients), and/or bone marrow biopsy may be taken.

- All initial specimens from any source should have AFB cultures performed.
 - Drug susceptibility testing should be performed on all initial TB complex isolates.
4. Airborne Infection Isolation (All) must be utilized for patients with previously diagnosed pulmonary or laryngeal TB, who remain on treatment, and are admitted to or seen at Duke until active TB is ruled out. Questions concerning prior TB treatment should be directed to the TB clinic at the patient's county health department. On weekends, holidays, or after hours when the health departments are closed, place the patient on All and contact the Infection Prevention nurse on call (DUH 919-970-9721; DRH 919-470-7171 or pager #7171; DRaH 919-954-3166).
 5. All is required for patients with respiratory smears positive for AFB where an alternate diagnosis has not been established or strongly suspected and PCR results are not available.
 6. All is required for any patient with active multi-drug resistant TB (MDR-TB). Isolation may not be discontinued without approval from an Infectious Disease physician and Infection Prevention.
 7. All is required for patients with known or suspected TB abscesses/wounds that are open/draining, have drains in place, or are undergoing dressing changes until two weeks of appropriate therapy has been completed AND approval from Infection Prevention has been obtained.
 8. For pediatric patients placed on All for known or suspected TB, their primary caregivers must be suspected as the source of the patient's infection until they are proven to be free of TB disease. Follow the Infection Prevention Policy, "Inpatient Management and Screening for Caregivers of Pediatric Patients with Known or Suspected Tuberculosis", found on the Duke Intranet.

B. Discontinuation of All

1. Three sputum smears, collected prior to the initiation of anti-tuberculosis medication therapy, and collected at least eight hours apart, of which one is an early morning specimen, are all negative.
 - Failed attempts to collect sputum specimens, with nursing supervision and documentation, will be followed by three attempts to collect induced sputum by nebulizer. If these attempts fail, and are documented, then All can be discontinued.
 - A smear negative Bronchoalveolar lavage (BAL) specimen counts as one negative AFB smear. Two additional negative smear results

(or negative attempts at sputum induction) are required to discontinue All.

2. PCR testing is negative on two sputum smear positive specimens.
3. An alternate diagnosis or explanation of symptoms exists and is documented by the attending physician in the patient's medical record.
4. An evaluation by an Infectious Disease physician has deemed TB unlikely. Patients have negative smears as described above and the suspicion for TB is not high. Patients on empiric TB therapy are to remain in isolation despite negative sputa until other criteria for discontinuation of TB therapy are met.
5. Patients with confirmed, active pulmonary or laryngeal TB who require continued hospitalization shall be kept on All until they are no longer infectious, defined as:
 - They have been compliant on tuberculosis medications to which the organism is judged to be susceptible for at least 14 days; AND
 - There is evidence of clinical response to tuberculosis treatment; AND
 - Three consecutive sputum smears collected at least eight hours apart are negative. For patients with initial smear-positive disease, these specimens should not be collected until after at least 14 days of treatment and 7 days from the last positive smear.
 - Failed attempts to collect sputum specimens, with nursing supervision and documentation, should be followed by three attempts to collect induced sputum by nebulizer. If these attempts fail, and are documented, and all other criteria are met, then All can be discontinued.
6. For wounds or open draining lesions that are culture positive for TB complex, All can be discontinued after the patient is on effective anti-tuberculosis treatment for two weeks AND approval from Infection Prevention has been obtained.
7. Under special circumstances, All may be discontinued at the discretion of Infection Prevention in collaboration with the IP Medical Director.

C. Discharge Planning Criteria

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

D. Inpatient All Precautions

1. All may be initiated by attending physicians, consulting physicians, triage nurses, inpatient nurses, physician assistants, nurse practitioners, the PHE, or Infection Prevention personnel. Orders initiated by a healthcare provider other than a physician are valid for 24 hours, during which time a physician must co-sign the orders or write an order to discontinue All.
2. Patients with known or suspected infectious TB will be housed in a designated All room (Appendix D) with the wearing of approved protective respiratory devices by all persons entering the patient's room. Approved respiratory devices are described in detail in VIII I, and include N95 respirators for those who are fit-tested and PAPRs for those who are not fit-tested and not working inside a sterile field. See Section VIII I for instructions on ordering PAPRs from Equipment Distribution.
3. Bacterial/viral filters will be used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
4. Patients placed on All will be instructed by their medical and nursing staff on the need to adhere to All policies and to cover their mouth and nose with tissues when coughing and sneezing.

5. Visitors of patients in All for suspected or confirmed pulmonary TB should be limited to immediate adult household members. Visitors are to wear the posted PPE, including N95 respirators, while in the patient's room. The patient's primary nurse is responsible for providing the visitors with instructions on how to wear the N95 respirators and how to perform a user seal-check (see appendix G) before allowing the visitors to enter the patient's room.
6. If a designated All room is not available (i.e., all are being used for All), or if it would not be medically appropriate to place the patient on one of the designated units (i.e., an obstetric or pediatric patient) then the patient will be placed in the back-up All room for the area they are in (Appendix D lists the designated and back-up All rooms). Designated All rooms and back-up All rooms have negative airflow capability and dedicated exhaust.
7. If an All room (designated or back-up) is not available or if the patient is in an area that lacks All rooms (e.g., Radiology) then a portable high-efficiency particulate air (HEPA) filter will be placed in the patient room (refer to Section VIII.G.2). The portable HEPA should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing, follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). For areas that do not have their own portable HEPAs, one can be ordered from Equipment Distribution through the Service Now Portal. For immediate needs or emergent situations call:
 1. The Equipment Distribution Hotline at 919-681-6097, 24/7 at DUH.
 2. Engineering at 919-470-4159 at DRH.
 3. Engineering at 919-954-3390 at DRaH.

*Infection Prevention should be notified of this room decision when housing patients.

8. Patients are to stay in their All rooms until infectious TB has been ruled out. The only time a patient may leave their room is if a necessary procedure must be performed outside of the All room. Patients who refuse to adhere to All policies will be reported to the appropriate County Health Department. Legal action may be taken to enforce appropriate All precautions when requested by the attending physician, the PHE, or Infection Prevention. The Duke Police will assist local law enforcement as needed in enforcing court-ordered isolation.
9. In the event that a patient with known or suspected TB must be transported to another area within the hospital for any reason, the patient must wear a surgical mask that covers the nose and mouth during the period of transport. Persons who transport such patients do not need to wear respiratory protection outside the All room while the patient is

wearing a mask. In instances where diagnostic testing must be done outside the All room, efforts to schedule the procedure at a time when it can be performed rapidly and without prolonged waiting are encouraged. In such instances, the receiving area will be notified that the patient requires All.

E. Outpatient All Precautions (Refer to Appendix B for Outpatient Clinic Guidelines)

1. Before a known TB patient arrives confirm that the patient is no longer infectious (by contacting the health department in the patient's county of residence) or reschedule the visit if medically possible. If a known infectious patient must come to the clinic, then the patient should be instructed to wear a surgical mask (or have wounds covered) when entering the building where the clinic is located and clinic staff should place the patient directly into the exam or procedure room and close the door – the patient should not spend any time in a waiting room with other patients or visitors. These precautions should also be taken with coughing children with known or suspected TB. For pulmonary disease, if the patient can wear a surgical mask during their entire visit employees do not need to take respiratory precautions.
2. If the suspicion of infectious TB disease is discovered during a clinic visit, place a surgical mask on the patient as soon as possible and close the exam door. Contact the health department in the patient's county of residence and make plans to refer the patient (after hours contact a local Emergency Department, if medically indicated). Keep the patient in an exam room with the door closed until the patient can be referred. Once the patient leaves, the room must be kept empty with the door shut for two hours to provide appropriate ventilation time. In a medical emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not (however, employee must perform and pass a user seal check).
3. To discontinue All precautions for a patient in the clinic see appendix B.
4. Before discontinuing All precautions for subsequent clinic visits by the patient, clinic personnel should obtain verification that the patient is receiving effective therapy and is no longer infectious by contacting the health department in the patient's county of residence.
5. In Duke clinics, if the patient cannot wear a surgical mask for the entire visit:
 - a) If an All room is not available, a portable HEPA should be placed in the exam or procedure room where the patient will be seen (refer to

Section VIII G 2). The portable HEPA should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). If a clinic does not have a portable HEPA unit assigned to it, one can be ordered through the Service Now Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097 (DUH) or 919-470-4159 (DRH) or 919-954-3166 (DRaH), 24/7).*

- b) All employees entering the room or enclosed area where there is a patient who is not wearing a surgical mask and has known or suspected tuberculosis must wear an appropriate respiratory protection device. Proper protective respiratory devices are described in detail in Section VIII.I and include N95 respirators for those employees who are fit-tested and PAPRs for those who are not fit-tested. If PAPRs are needed in an area where they are not stocked or if additional PAPRs are needed they can be obtained through the Service Now Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097 (DUH) or 919-470-4159 (DRH), or 919-954-3390 (DRaH) 24/7).* The disposable head coverings are ordered from Material Services. In unanticipated events with an unmasked patient a N95 respirator is appropriate temporary protection whether the employee is fit-tested or not (and employee performs and passes user seal check).

F. Emergency Medical Service:

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

G. Engineering Controls

- 1) All Rooms – Inpatient (Refer to Appendix D for All Room Instructions)
 - a) 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.

- b) 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).
- c) Negative pressure is tested daily when a patient is on All precautions by the care nurse using the tissue test and documented on the “Negative Air Pressure Test Log” (see Appendix E). This log is maintained on each nursing unit, procedure area, or clinic.
- d) Monthly air pressure testing by manometer is performed by E&O. This record is maintained by OESO. In addition, a list of All rooms (See Appendix C) will be maintained by OESO and provided to Bed Control, departmental managers, nurse managers, the PHE, and Infection Prevention. It is the responsibility of OESO to maintain records on the monthly testing and utilization of these isolation rooms and to notify the ICCs of deficiencies and inadequacies of ventilation controls.

2) Portable High-Efficiency Particulate Air Filter Units

- a) On-site hospital and clinics, and at any off-site clinics that have them, portable high-efficiency particulate air (HEPA) filter units will be used in the control of tuberculosis in known or suspected cases of infectious tuberculosis in any area where such patients may be roomed and recommended All ventilation is not available. Infection Prevention of specific entity will be notified in these situations.
- b) The portable HEPA should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). OESO will be responsible for education concerning the proper utilization and maintenance of such devices. Portable HEPAs are available from Equipment Distribution through the Service Now Portal. *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097 (DUH), 919-470-4159 (DRH), and 919-954-3390 (DRaH). 24/7).*
- c) OESO has the responsibility for providing on-call advice concerning the use and advisability of such units and for preparing and maintaining the “Portable HEPA Operating Instructions” sheet mentioned above. Clinical Engineering is responsible for the electrical safety and motor performance of the units. The biological safety cabinet certification contractor for the university and health system (on contract through Duke University Procurement Services) provides

annual certification and service which includes monitoring and changing the filters as necessary.

H. High Hazard Procedures:

- 1) Cough-inducing procedures (e.g., bronchoscopy, sputum collection, sputum induction, aerosolized pentamidine treatment, etc.) on patients with known or suspected tuberculosis should be performed in rooms that meet the ventilation requirements as outlined for All rooms (Section VIII.G.1 and Appendix D).
 - a) If such rooms are not available, supplemental control devices such as isolation booths or portable HEPA's must be employed (refer to Section VIII.G.2 for information on portable HEPA's). Portable HEPA's should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)).
 - b) 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.
 - c) 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.
 - d) Employees must wear respiratory protection while cough-inducing procedures are performed on patients with known or suspected tuberculosis (see Section VIII.I).
 - e) Patients with known or suspected tuberculosis who are recovering from sedatives or anesthesia following procedures such as bronchoscopy must be monitored in a separate All room or be recovered in the procedure All room.
 - f) After the patient leaves the treatment or procedure room, the room should remain closed for 30 minutes. Any staff members needing to enter the room during this time period will need to wear appropriate PPE and a HEPA filter should be left running.
- 2) Aerosol-Generating Procedures:
 - a) Autopsy rooms should meet the criteria for All rooms in Section VIII.G.1. They must be at negative pressure with respect to adjacent areas and the room air should be exhausted directly to the outside of the building because infectious aerosols are likely to be present. Respiratory protection must be worn by personnel [and a portable HEPA unit must be running](#) while performing autopsies on deceased persons who may have had TB at the time of death (see Section VIII.I).

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

I. Respiratory Protection Program Policy

- 1) Background: The “Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities” were first published by the CDC in October 1994. These recommendations, specified that respiratory protection be provided for employees that have the potential to be exposed to TB aerosols. Duke’s *TB Exposure Control Plan* was developed in response to this CDC guideline. Beginning January 1, 2005 the use of respirators for protection against TB Complex is regulated by [OSHA Standard 29 CFR 1910.134](#) Respiratory Protection. In accordance with this OSHA standard, Duke modified the [Duke Respiratory Protection Policy](#) to include TB and developed the [Respiratory Protection Policy for TB, SARS, and Other Airborne Particulates in Clinical Settings](#). Then, in May 2019, the CDC published an updated version of their guidelines titled “Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019,” 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. Employees included in the program receive medical clearance, training on respirator usage, and fit-testing to select an appropriately fitting respirator. Students receive their training and fit testing through the Student Health Center.
- 2) In order to minimize the number of persons who must participate in the Respiratory Protection Program, every effort will be made to cluster patients on All onto the designated TB nursing units. See Appendix C for list of appropriate All rooms. Personnel included in the program will include, but are not limited to, personnel listed in Appendix E that may have direct contact with a patient on All or the potential to be exposed to TB aerosols generated during high hazard procedures.
- 3) Appropriate respiratory protection must be worn by all personnel in the following situations:
 - a. To enter an enclosed area with a known or suspected active pulmonary TB patient.

- b. To perform or assist in cough inducing procedures such as bronchoscopy or the delivery of aerosolized pentamidine treatments on patients with known or suspected TB
 - c. To mix or administer BCG outside of a biological safety cabinet.
 - d. To perform or be exposed to TB aerosol-generating procedures in the autopsy suite or clinical laboratory
 - e. To access the air handling system before the air has passed through the HEPA filter (Entity engineering employees only)
- 4) Appropriate respiratory protection is defined as:
- a. An N95 respirator (for which the user has passed a fit test)
 - b. A PAPR, if the user does not have a fit-tested N95 respirator available or is unable to wear an N95
- 5) The Respiratory Protection Program for TB is administered by OESO, EOHW, and Student Health.
- 6) Respirator Approval Process:
- a) The approval process requires EOHW review of a questionnaire screening for medical conditions that may preclude respirator usage. A medical evaluation may be required based on the results of the screening. Employees must complete a new screening questionnaire if they report a change in their medical condition when they take their annual training or at their annual fit-testing.
 - b) Training includes information on the purpose, proper use, donning and doffing, storage, handling, and limitations of the respiratory protective devices.
 - c) N95 respirator fit-testing is required in accordance with OSHA regulations and involves matching a mask model and size to each individual's face and measuring inward leakage potential during use conditions. Personnel who have already been fit-tested at another institution within the last year do not need to be retested as long as they can provide adequate documentation and were fitted with one of the respirators available at Duke.
 - d) Upon successful completion of medical clearance, annual training, and fit-testing (in accordance with OSHA regulations), each individual is approved to wear a specific respirator (make, model and size). Employees may only wear the respirator for which they have been approved. Substitution by manufacturer, size, or model is not allowed.
- 7) The N95 respirator:

- a) A list of personnel requiring N95 respirator fit-testing can be found in Appendix E. Employee fit-testing for airborne pathogens is performed by OESO/EOHW or other staff trained by OESO. Students needing respiratory protection are fitted by Student Health or other trained staff.
 - a. The primary respiratory protection device is the N95. Every effort will be made to qualify all employees covered under the respiratory protection program with the N95 (i.e., have them pass a fit test). It is important to note that these respirators are authorized for use in protecting employees from TB droplet nuclei.
 - b) Training on the proper use of N95s is required. On-line training is available at [OESO's Safety Training Website](#). The module is called "Respirator Training for Airborne Pathogens".
 - c) The N95 will be available at all rooms or areas housing patients who require All. The N95 respirator is approved for individual use only and cannot be shared between medical personnel working in the same area at different times. The same mask cannot be used by an employee when caring for different patients. It can be reused with the same patient as long as: 1) it is properly stored, 2) it is not visibly contaminated, and 3) it is intact (i.e., not crushed or torn). Always refer to current infection prevention policies for up-to-date information on PPE usage.
 - d) Note: Employees must wear the N95 respirator that they were fit-tested for.
 - e) Employees will conduct a "user seal-check" prior to each use of the N95 respirator. See Appendix F.
 - f) Priority fit-testing for the N95 is possible for personnel who are not fit-tested and provide direct care to a patient on All when the patient cannot be moved to a fit-tested nursing unit for medical reasons. This decision will be made in collaboration with Infection Prevention, EOHW, and OESO.
 - g) Unanticipated use of an N95 respirator without fit-testing is appropriate with an unmasked patient. Patient care areas that have employees that are not fit-tested with the N95 respirator should keep a box of N95 respirators on hand. The seal check described in Appendix F should be performed prior to use.
- 8) Powered Air-Purifying Respirator (PAPR):

- a) A list of personnel designated as PAPR users can be found in Appendix E.
 - b) PAPRs cannot be used inside a sterile field or in MRI.
 - c) The PAPR will be used by all employees that fail or are unable to be fit-tested with an N95 mask including those employees with facial hair interfering with the sealing surface of the N95.
 - d) Training on the proper use of the PAPR is required and is provided by OESO. On-line training for the PAPR is available at [OESO's Safety Training Website](#). The module is called "Respirator Training for Airborne Pathogens".
 - e) PAPRs are located
 - i. For DUH: in the Equipment Distribution Department and can be ordered through the Service Now Portal. (*For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097, 24/7*). The disposable head coverings are ordered from Material Services.
 - ii. For DRH: on each medical unit, in the ED, and can be obtained through the Operations Administrator (OA).
 - iii. For DRaH: located and maintained on each medical unit, in the ED, and can be obtained through Engineering 919-954-3390.
- 9) 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.
- 10) Monitoring: Access to respiratory protection compliance summaries will be provided to supervisors and managers. Failure of designated personnel to comply with the Respiratory Protection Program constitutes a violation of Duke policy. Employees can check their compliance with respiratory protection training, fit-testing and medical clearance requirements by logging onto OESO's Safety Training website.

IX. APPENDICES

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

1) County Health Departments

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

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

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

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

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

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

- 1) Case Report: Licensed physicians report cases and suspected cases of reportable communicable diseases and conditions in persons who have consulted them professionally (see above).
- 2) Laboratory Report: Each smear positive for acid-fast bacilli and each specimen or culture positive for TB Complex should be reported within seven days of obtaining the result. The completed report is sent to: DHHS, Division of Epidemiology, Tuberculosis Branch, PO Box 27687, Raleigh, NC 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) TB.
 - 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 TB status as a public health precaution. Such a person should have a reasonable possibility of having an infectious form of TB.

Appendix B: Clinic Visits from Known or Suspected TB Patients

1. Known Infectious TB Patient is Coming to the Clinic

- a. Notify entity specific infection preventionist
- b. Infectious TB Patients are defined as:
 - i. Smear-positive pulmonary TB
 - ii. Wounds or open-draining lesions that are uncovered
- c. Smear-positive pulmonary TB can be considered non-infectious if either of the following are true:
 - i. There are 2 negative sputum smears collected at least 8 hours apart
 - ii. Patient is clinically improving and is on effective drug therapy for at least 2 weeks
- d. Schedule visit for when the patient will not have to wait and when the fewest other patients are scheduled
 - i. Think about patient placement in the clinic or room, such as isolating the patient from other patients and employees and close to an exit so infectious TB patient doesn't have to walk around the clinic
- e. Instruct pulmonary TB patient to wear a surgical mask when entering the building and to keep it on for the duration of the visit
- f. Place patient directly into exam room and keep door closed
 - i. If a portable HEPA unit is available, place it in the room with the patient
- g. After discharge:
 - i. If patient wore a surgical mask, then routine procedures are used to clean the room
 - ii. If patient did not wear a surgical mask and a HEPA unit was used, the room must sit empty with the door closed for 30 minutes
 - iii. If patient did not wear a surgical mask and a HEPA unit was not used, the room must sit empty with the door closed for 120 minutes
 - iv. Do not enter the room without respiratory protection during the 30 or 120 minute time frame

2. Patient in the Clinic has Signs or Symptoms of Active Pulmonary TB

- a. Instruct patient to wear a surgical mask as soon as possible
- b. Notify entity-specific infection preventionist
- c. Place patient directly into exam room and keep door closed
 - i. If a portable HEPA unit is available, place it in the room with the patient

- d. After discharge:
 - i. If patient wore a surgical mask, then routine procedures are used to clean the room
 - ii. If patient did not wear a surgical mask and a HEPA unit was used, the room must sit empty with the door closed for 30 minutes
 - iii. If patient did not wear a surgical mask and a HEPA unit was not used, the room must sit empty with the door closed for 120 minutes
 - iv. Do not enter the room without respiratory protection during the 30 or 120 minute time frame

- e. Contact the Health Department in the patient's county of residence to discuss the plan of care

Appendix C: Airborne Infection Isolation (All) Rooms

High-Hazard / Cough-Inducing Procedure Rooms

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

Designated All Rooms

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

DUH

Duke North	DMP	DCT
2101	6W 9, 10, 11, 12, 13, 14, 15, 16	6DCT 16, 17
2332	6E 9, 10, 11, 12, 13, 14, 15, 16	
4332	8W 13, 14, 15, 16, 17, 18, 19, 20	
5101, 5131		
5610		
8101		
8332		

DRH

Duke Regional
4121
5200
5214
7121
CCU 6, 7
ED 27, 28
DRI 7301

DRaH

North Pavilion	South Pavilion	ED	Peri-procedural
2201	2709, 2710, 2718, 2719, 2727, 2728	5, 12, 14	Endo 1 (Bronch suite)
3201	3709, 3710, 3718, 3719, 3737, 3728		Room 32 (Same day Surgery)
4201	4709, 4710, 4718, 4719, 4727, 4728		Room 40 (PACU)
5201			

Back-up All Rooms

These rooms are to be used only if all possible designated TB All rooms are being used for patients on All or if it is medically necessary that the patient stay on that unit. Contact Infection Prevention (919-684-5457 or 970-9721) for approval. Employees not fit-tested for an N95 respirator must use the PAPR for respiratory protection.

Duke North	DMP	DCT
3101	7W 13, 14, 15, 16, 17, 18, 19, 20	1A16
3332	7E 9, 10, 11, 12, 13, 14, 15, 16	1A17
4101	8E 9, 10, 11, 12, 13, 14, 15, 16	2A16
4216		2A17
5509		3A16
5809		3A17
6332		4A16
7101		7A16
7332		7A17
7717		8A16
7822		8A17
7831		9A16
7833		9A17
7834		10A16
9101		10A17
9201		
9332		

Appendix D: Patient Care Airborne Infection Isolation Room Instructions

1. NURSING PERFORMS THE TISSUE TEST EACH DAY that airborne precautions are in place. Local protocols may require more frequent testing. Hold a small piece of tissue in front of the door ~1” above the floor outside of the room. Slightly crack glass sliding doors. The tissue should be pulled towards the room at *all* doors including the anteroom door/s.
 - ◆ If there is a key switch above the main patient door, it should be set to negative (-).
 - ◆ If there is an air-ball indicator make sure the ball is pulled into the room (unable to see from outside the room).
 - ◆ Document the tissue test result on the “Tissue Test Log for Negative Air Pressure”, below. A notebook of these completed forms must be kept in the area or unit.
2. **If the room is not operating correctly or you need assistance call your local Engineering:**
 - ◆ **DUH: E&O at 919-684-3232**
 - ◆ **DRH: 919- 470-4159**
 - ◆ **DRaH: 919-954-3390**
3. CLOSE ALL DOORS AND KEEP THEM CLOSED WHEN ROOM IS IN USE FOR AIRBORNE ISOLATION:
This is necessary to maintain negative airflow .
4. PLACE AIRBORNE INFECTION ISOLATION SIGNS ON THE DOORS TO THE PATIENT ROOM AND ANTEROOM. Additional signs can be ordered through the SAP system.
5. STOCK RESPIRATORY PROTECTION IN THE ANTEROOM FOR USE BY EMPLOYEES AND VISITORS:
 - ◆ N95 Respirators
 - ◆ Powered Air Purifying Respirators (PAPRs) for those who are not fit-tested for an N95 (Note: PAPRs cannot be used inside a sterile field or in MRI):
 - PAPRs are plugged into the charger when not in use.
 - DUH: PAPRs can be ordered through the Service Now Portal.
✓ *(For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097, 24/7).*
 - DRH: PAPRs are found on the patient units
 - DRaH: PAPRs are ordered through Facilities 919-953-3390
 - Use only appropriate PAPR Head Covers (Remove film before first time use.)
6. EMPLOYEES WEAR APPROVED RESPIRATORY PROTECTION TO ENTER AIRBORNE ISOLATION ROOM
 - ◆ An annual fit-test by EOHW/OESO is required to use an N95 respirator, otherwise use a PAPR.
 - ◆ Perform a user “seal-check” each time you wear an N95 respirator.
 - ◆ In an emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not (and employee performs and passes user seal check).
7. THE PATIENT SHOULD WEAR A SURGICAL MASK IF TRANSPORT OUTSIDE OF THE ROOM IS ESSENTIAL
 - ◆ Inpatients on airborne isolation are not to leave their room unless medically necessary or Infection Prevention has given approval.
 - ◆ Transporters are not fitted for the N95 respirator. Bring the patient out of the airborne isolation room to them.
8. VISITORS SHOULD WEAR N95 RESPIRATORS (WITHOUT FIT-TESTING)
 - ◆ Nursing should provide instruction to visitors on how to perform the N95 user seal-check and how to properly wear and discard the N95 respirator.
9. NOTIFY INFECTION PREVENTION:
 - ◆ 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.
 - ◆ DUH: 919-684-5457 (or 919-970-9721 after hours)
 - ◆ DRH: 919-470-7171 (0800-1700)
 - ◆ DRAH: 919-954-3166 (or pager 919-206-3311 after hours)
10. KEEP DOORS CLOSED FOR AT LEAST 30 MINUTES AFTER AN AIRBORNE INFECTION ISOLATION PATIENT LEAVES THE ROOM:
 - ◆ If the patient is discharged while still on isolation or the patient is having a procedure performed elsewhere in the hospital or clinic.
 - ◆ Respiratory protection must be worn to enter the room before this time is up and all the doors must remain closed.

**DUH AIRBORNE INFECTION ISOLATION ROOM
TISSUE TEST LOG FOR NEGATIVE AIR PRESSURE**

Room: _____

Unit: _____

Date	Negative Air Pressure Validated	Initials	Date	Negative Air Pressure Validated	Initials
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	
	Y N			Y N	

- **Notify Engineering immediately if room fails negative pressure check at:**
- **DUH: 919-684-3232**
- **DRH: 919-470-4159**
- **DRaH: 919-954-3390**
 - **Ask patient to wear surgical mask until the patient is transferred to another airborne isolation room, a portable HEPA is placed in the room, or the negative pressure is restored by E&O or other entity Engineering group.**
 - **Test room again when repair is completed.**
- **File this completed form in Tissue Test Notebook kept on the unit when airborne precautions are discontinued or the patient is discharged.**

Appendix E: Personnel Requiring Respiratory Protection

Personnel Requiring N95 Respirator Fit-Testing

- Healthcare workers in the following areas (including nurses, PAs, NPs, House Staff, and EVS workers):

DUH	DRH	DRaH
DN 2100	4-1 General Medicine	All inpatient units
DN 2300	5-1 General Medicine	Emergency Dept + unit coord.
DN 4300	5-2 Telemetry	Bronchoscopy/Endo suite
DN 5100	5-3 Neuro/Oncology	Cardiac Cath lab
DN 5600	6-3 General Surgery	Adult Oncology Treatment Ctr
DN 7800	7-1 Orthopedic/Neuro	Respiratory Care
DN 8100	Hemodialysis	Radiology
DN 8300	ICU	In-patient Phlebotomy
DMP 6E	Emergency Dept + unit coord.	Vascular Access Team
DMP 6W	Endoscopy	In-patient Dialysis
DMP 8W	Radiology	Perfusionists
DCT 6	Respiratory Therapy	Social Workers
DS 1K	Vascular Access Team	Case Managers
DS 2A	Women's Services	
DS 2P	PT	
DS 2F/2G	Infectious Disease	
CC Oncology Treatment Ct	Pulmonary	
CHC 2 (Peds ID and Pulm)		
Emergency Dept		
Life Flight		
Bronchoscopy Adults & Peds		
RT/PFT + equip. handlers		
Radiology		
Vascular Access Team		
In-patient Phlebotomy		
CDU		
In-patient Dialysis		
Perfusionists		
IP		

- o All off-site pulmonary clinics

- Select Personnel in these areas (supervisor will designate)

DUH	DRH	DRaH
Clinical Microbiology	CNA (float pool)	Surgical Services
Bone Marrow biopsy staff	Surgical Services	Clinical Microbiology
Pathology	Environmental Services	Bone Marrow biopsy staff
Cytology	Engineering	Pathology
E&O	Cytology/Hematology	Cytology
PT/OT	Phlebotomists	Engineering
CNA (float pool)	Pulmonary Function Testing	PT/OT
Autopsy MDs	Bone Marrow biopsy staff	
	Interpreters	

- Housestaff assigned to work in the following specialty groups/programs:
 - Emergency Department (part of Surgery/Trauma)
 - Infectious Disease (Adult and Peds)

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

Personnel Designated as PAPR Users

DUH	DRH	DRaH
Those who fail the N95 fit-test	Those who fail the N95 fit-test	Those who fail the N95 fit-test
Those who have beards or other facial hair that interferes with the fit of the N95	Those who have beards or other facial hair that interferes with the fit of the N95	Those who have beards or other facial hair that interferes with the fit of the N95
In-patient Dialysis	In-patient Dialysis	In-patient Dialysis
Patient Advocates	Patient Advocates	Patient Advocates
Selected Pastoral Care employees	Selected Pastoral Care employees	Selected Pastoral Care employees
Autopsy personnel		Autopsy personnel
Neurodiagnostics techs		Neurodiagnostics techs
Interpreters (International Patient Center)		Interpreters (International Patient Center)
Speech Pathology Staff		Speech Pathology Staff
Social Workers/Case Managers	Social Workers/Case Managers/Resource Center	
DUHS Float Pool RNs & CMAs	RN's working in Float Pool	
Hospital-based ECG technicians and Physiological Monitoring Cardiology Techs (Central Telemetry)	Hospital-based ECG technicians	
<u>Low-risk Radiology on-site</u> departments: <ul style="list-style-type: none"> • Clinic-Based Diagnostic X-Ray (2E, 1B/1C, 1G, 1H & CC), Clinic-Based CT (CC), Pet Scan, Nuclear Med, Peds • Note: MRI Techs & Mammography are not classified as needing respiratory protection 	Radiology Mammography/Ultrasound	
	DRH Safety Officers	
	Infection Prevention	
	Operations Administrators	
	DHTS	

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

POSITIVE PRESSURE FIT CHECK



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

REMOVAL:



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



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



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

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

3M Canada
Post Office Box 5757
London, Ontario N6A4T1
Canada
1 800-563-2921
Outside of USA, please contact your 3M Representative

Please Recycle

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70-2009-0557-1



Helping You Wear it Right

3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+

Application

Always read and follow User Instructions.



1 Remove the respirator from its packaging and hold with straps facing upward. Place the bottom strap under the center flaps next to the "ATTENTION" statement.



2 Fully open the top and bottom panels, bending the nosepiece around your thumb at center of the foam. Straps should separate when panels are opened. Make certain the bottom panel is unfolded and completely opened.



3 Place the respirator on your face so that the foam rests on your nose and the bottom panel is securely under your chin.



4 Pull the top strap over your head and position it high on the back of the head. Then, pull the bottom strap over your head and position it around your neck and below your ears.



5 Adjust for a comfortable fit by pulling the top panel toward the bridge of your nose and the bottom panel under your chin. Make certain hair, facial hair, jewelry and clothing are not between your face and the respirator as they will interfere with fit.



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



Perform a User Seal Check

Check the seal of your respirator each time you use the respirator.

Place one or both hands completely over the middle panel. Inhale and exhale sharply. Be careful not to disturb the position of the respirator. If air leaks around your nose, re-adjust the nosepiece as described in Step 6. If air leaks around respirator edges, adjust panels and position of straps and make certain respirator edges fit snugly against the face. **If you cannot achieve a proper seal, do not enter the contaminated area. See your supervisor.**

Removal Can be performed using one or both hands



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



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



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

3M Health Care
Medical Solutions Division
2510 Conway Avenue
St. Paul, MN 55144-1000
U.S.A.
1-800-228-3957
3M.com/Medical

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WARNING

Respirators help protect against certain airborne contaminants. Before use, the wearer must read and understand the User Instructions provided as a part of the product packaging. Follow all local regulations. In the U.S., a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134 including training, fit testing and medical evaluation. In Canada, CSA standards Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Misuse may result in sickness or death. For correct use, consult supervisor and User Instructions, or call 3M Personal Safety Division (PSD) Technical Service in the U.S.A. at 1-800-243-4630. In Canada, call 1-800-267-4434.



PROPER WEARING OF HALYARD* N95 PARTICULATE FILTER RESPIRATORS AND SURGICAL MASKS

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

NOTE: When using a FLUIDSHIELD* N95 Particulate Filter Respirator, the orange side MUST be worn facing outward and upward in order to provide fluid-resistant protection.

Directions for Proper Donning: Properly donning your 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 right when applying this respirator.

Tips for Achieving a Good Fit: If you have a problem successfully user seal checking 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 after trying these tips you are still unable to successfully user seal check your respirator, see your supervisor or respiratory protection coordinator.

DO NOT PROCEED WITH YOUR ACTIVITIES UNTIL YOU HAVE SUCCESSFULLY USER SEAL CHECKED YOUR RESPIRATOR!!

For more information, please visit:
www.halyardhealth.com

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1 Separate the edges of the respirator to fully open it.



2 Slightly bend the nose wire to form a gentle curve.



3 Hold the respirator upside down to expose the two headbands.



4 Using your index fingers and thumbs, separate the two headbands.



5 While holding the headbands with your index fingers and thumbs, cup the respirator under your chin.



6 Pull the headbands up over your head.



7 Release the lower headband from your thumbs and position it at the base of your neck.



8 Position the remaining headband on the crown of your head.



9 Conform the nosepiece across the bridge of your nose by firmly pressing down with your fingers.



10 Continue to adjust the respirator and secure the edges until you feel you have achieved a good facial fit. Now, perform a user seal check.

DIRECTIONS FOR USER SEAL CHECKING

IT IS IMPORTANT TO USER SEAL CHECK THE RESPIRATOR EVERY TIME YOU WEAR IT.

Forcefully inhale 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 facial fit. Adjust the respirator until the leakage is corrected and you are able to successfully user seal check your respirator.

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

- 1) Because the Operating Room (OR) has recirculated air under positive pressure, surgery on patients with known or suspected TB should be postponed until TB has been ruled out or the patient is determined to no longer be infectious.
- 2) If surgery cannot be postponed then a portable HEPA must be placed in the room from the time the patient enters the room until a minimum of 30 minutes after final cleaning. In Duke Hospital OR use one portable HEPA per suite and in the DMP OR use two portable HEPAs per suite. The portable HEPAs should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)).
- 3) The case should be scheduled as the last case of the day.
- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) An N95 respirator (or a PAPR if the employee works outside the sterile field and is not fit-tested) must be worn for cases of known or suspected TB. In cases where TB is suspected before the surgery, every effort will be made to identify those staff that will be working in the particular OR suite and provide them with N95 respirator fit-testing prior to the procedure if they have not been fit tested.
- 6) If TB is not suspected until after surgery begins, staff should immediately replace their standard surgical masks with an N95 respirator. The N95 respirator provides acceptable temporary protection whether the employee is fit-tested or not (if employee performs and passes user seal check).
- 7) During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended ventilation standards for TB isolation rooms (PACU isolation rooms are listed in Appendix D) or remain in the Operating Room with the portable HEPA filter still running.

In cases of known multi-drug resistant tuberculosis that require surgery, contact Biological Safety (919-684-8822) for coordination of additional engineering controls to be implemented by the Engineering and Operations or other entity Engineering HVAC division. Also contact EOHW/OESO to arrange for N95 respirator fit-testing for those employees working within the sterile field if they have not been fit tested. The details for this protocol can be found in the Operating Room Safety Manual.

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

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

If the procedure cannot be postponed then a portable high efficiency particulate air (HEPA) filter must be placed in the room from the time the patient enters the room until after the room has been cleaned following the case, a minimum of 30 minutes after final cleaning. The portable HEPA filter should be turned on and off following the instructions on the instruction sheet accompanying the unit (if the instructions are missing follow this hyperlink to the document: [Portable HEPA Operating Instructions](#)). Portable HEPAs are ordered through the Service Now Portal. (*For immediate needs or emergent situations call the Equipment Distribution Hotline at 919-681-6097, 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 respirators (or PAPRs if that employee only works outside the sterile field). In areas of low risk for TB transmission, routine fit-testing for the N95 respirator is not required. In cases whereby suspicion for TB arises during a procedure, staff should replace their standard surgical masks with an N95 respirator. A user seal-check should always be performed when donning an N95. The N95 respirator provides acceptable temporary protection whether the employee is fit-tested or not (if employee performs and passes user seal check). In cases where TB is suspected before the procedure, every effort will be made to identify those staff that will be working that particular case and, if they are not fit-tested within the past year, provide them with N95 respirator fit-testing prior to the procedure.
- 6) During transport the patient is to wear a surgical mask. If possible, and the patient is not intubated, the patient is to wear a surgical mask during the entire procedure.

X. References

- A. Occupational Safety and Health Administration Respiratory Protection Standard [29 CFR 1910.134](#)
- B. Duke University Health System's [Safety Manual Respirator Policy](#)
- C. [The Respiratory Policy for TB, SARS, and Other Airborne Particulates in Clinical Settings](#)
- D. Centers for Disease Control and Prevention, "[Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005](#)"
- E. Centers for Disease Control and Prevention, "[Core Curriculum on Tuberculosis, What the Clinician Should Know](#)" Fourth Edition, 2000"
- F. NC TB Control Program Policy Manual [NC DPH: N.C. Tuberculosis Policy Manual](#)
- G. Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. *MMWR Morb Mortal Wkly Rep* 2019;68:439–443. DOI: <http://dx.doi.org/10.15585/mmwr.mm6819a3>