

SECTION VI.	Biological Safety
Chapter 2	Tuberculosis Control Plan
Revision Date	3/2009

TUBERCULOSIS CONTROL PLAN
(first approved July, 1995)

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

Preface

The primary purpose of this document is to detail a Tuberculosis Control Plan for Duke. In addition, a selected number of appendices are included to provide more detail and quick access to supporting information for this Plan.

This Plan was approved by the Hospital Infection Control Committee and Medical Center 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, and March 2009.

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1) 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 control, and patient care.

2) OVERVIEW OF INFECTION CONTROL MEASURES

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

3) 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 Control will maintain records summarizing the results of all investigations of health care workers and patients with known or suspected exposure to *Mycobacterium tuberculosis* (*M. tuberculosis*).

B) EOHW will provide reports to the Hospital Infection Control committee (HICC) every six months that include, along with appropriate demographic information, the number of hospital employees with known or suspected occupational exposure to TB, the number of employees who had a tuberculin skin test (TST) and their baseline status, the number of

employees who converted their TST after a known or suspected exposure to a patient with active tuberculosis, and the number of employees with suspected exposure who were lost to follow-up.

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

- 1) Current employees who had annual TST screening.
- 2) Employees who have had a TST conversion.

D) Infection Control and the Public Health Epidemiologist (PHE) in the Infectious Disease department (who serves as our liaison with the State Public Health system) will maintain a registry of all patients with documented infectious tuberculosis. A report will be made regularly to the HICC providing information, including appropriate demographic information, concerning the following:

- 1) Patients with microbiologically documented tuberculosis who were placed in isolation.
- 2) Patients with microbiologically documented tuberculosis who did not get placed in isolation for a period of time.

E) Biological Safety will summarize the following in written reports:

- 1) Employees who have not complied with the on-hire or annual requirement for a screening TST.
- 2) The TST conversion incidence by job location and/or job description (whichever is more appropriate). This information is provided to Biological Safety by EOHW and will be used for risk assessment.
- 3) The total number of days of isolation for:
 - a) tuberculosis, and
 - b) suspected tuberculosis
- 4) An analysis of nosocomial tuberculosis exposures and any evidence of trends or unusual circumstances. Individual cases will be investigated and reported describing the factors leading to such exposures with recommendations for preventing future exposures whenever possible.

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

Airborne Pathogens:

- 0) No likely or anticipated exposure to *M. tuberculosis*.
- 1) Work assignment for all or part of the employee's scheduled work time in areas where there is a risk of exposure to TB aerosols (e.g., patient care areas). New hires to these areas are evaluated by EOHW for infection with *M. tuberculosis*.
- 2) Work assignment is in a high risk area and employee is an N95 respirator user (See Appendix F).
- 3) Work assignment is in a high risk area and employee is a PAPR respirator user (See Appendix F).
- 4) Work assignment is in a high risk area and employee is evaluated annually by EOHW for infection with *M. tuberculosis* (See Appendix E).

Animal Contact:

- 0) No exposure.
- 1) Animal contact.
- 2) Works with non-human primates.
- 3) On protocol – no animal exposure.

IV) RESPONSIBILITIES

A) Employees

- 1) All employees with exposure determinations of Airborne Pathogens 1 – 4 and Animal Contact 2 are expected to complete required educational online programs concerning tuberculosis control and comply with tuberculosis control policies outlined in this plan. Employees with a designation of Airborne Pathogens 2 or 3 and Animal Contact 2 must comply with the requirements of the Respiratory Protection Program Policy for TB (see Appendix F).

- 2) Employees will report any incidents of possible exposure to tuberculosis to EOHW or Biological Safety.

B) Department Managers

- 1) All department managers will document each of their employees' compliance with the Duke's tuberculosis policies (including the Division of Laboratory Animal Resources policies and procedures) and compliance with Infection Control and/or Biological Safety tuberculosis educational programs on their yearly performance evaluation.
- 2) Assure that appropriate respiratory protection is available in facilities that house non-human primates.

C) Hospital Infection Control Committee (HICC)

- 1) The HICC will at least annually review all tuberculosis control activities provided to the Committee by Infection Control, the PHE, Biological Safety, and EOHW. Thereafter the HICC will report these findings to the Executive Committee of the Medical Staff.
- 2) The Chairman of the HICC will review and then arbitrate any controversies or disagreements over proper isolation of individual patients with known or suspected tuberculosis. The authority for this activity is outlined in the bylaws of the Duke Hospital and Clinics Medical Staff. These bylaws specifically state the Chairman of the HICC has the responsibility and authority to mandate specific isolation should disagreement occur between Duke Hospital and Clinics physicians and personnel from Infection Control or the PHE.
- 3) The Chairman of the HICC will be notified of any investigations of tuberculosis exposure of employees and students undertaken by Biological Safety and/or EOHW.
- 4) The HICC and the Duke University Safety Committee will review the TB Control Plan at least annually.

D) Infection Control and the PHE

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

used with Airborne Isolation. **On-call advice is available 24 hours a day, 7 days a week by calling Infection Control or the PHE at 684-5457 (pager 970-9721).**

- 2) Maintain a registry of all patients with infectious tuberculosis.
- 3) Participate (in conjunction with OESO and EOHW) in the orientation and continuing education of all new and current employees concerning tuberculosis control policies.
- 4) In conjunction with OESO and EOHW review the tuberculosis control plan annually.
- 5) Assess the risk of transmission of tuberculosis to employees by periodically reviewing the records of all patients with infectious tuberculosis and reporting the following information to the HICC:
 - a) Patients with infectious tuberculosis who had delays in the institution of Airborne Isolation and the duration of such delays.
 - b) Patients with infectious tuberculosis who had Airborne Isolation discontinued prematurely.
- 6) Report or assist in reporting all cases of known or suspected tuberculosis to the patient's county of residence health department. In turn, the health department will notify the NC Department of Health and Human Services. (Appendix A)
- 7) Notify Biological Safety of all patients placed in isolation for suspected or confirmed infectious tuberculosis, all positive AFB smears in patients with suspected infectious tuberculosis, and all *M. tuberculosis* positive cultures.

E) Biological Safety/OESO

- 1) OESO in conjunction with EOHW, the PHE, and Infection Control will assess the potential of each Duke employee for occupational exposure to TB. This assessment will include a review of each employee's work responsibilities with particular reference to their likelihood for occupational exposure to TB. (see III E)
- 2) Educate all area supervisors of the requirement that this assessment be completed on all employees.
- 3) Collate, organize and provide data on exposure determinations and provide department managers and supervisors with access to

reports regarding employee compliance to the requirements associated with their assigned exposure determination. Reports are also provided to EOHW, HICC, and the Safety Committee as needed.

- 4) Provide, document, and be responsible for any OSHA-required TB control training programs at Duke. This includes training at orientation and annual update training. All employees with exposure determination ratings of Airborne Pathogens¹ through 4 and Animal Contact 2 shall receive annual education concerning tuberculosis control. Those employees with exposure determinations of Airborne Pathogens 2 or 3 and Animal Contact 2 will receive annual respirator training.
- 5) Assure that appropriate ventilation or other engineering controls required by this plan are provided as needed (i.e., monitoring isolation room air pressure).
- 6) Assure that appropriate respiratory protection is available on all units caring for a patient on Airborne Isolation for TB.
- 7) Identify potentially exposed employees and students and provide this list to EOHW for further evaluation.
- 8) Manage and conduct annual reviews of the Respiratory Protection Program Policy for TB.

F) Employee Occupational Health and Wellness (EOHW)

- 1) New Employee Screening – New employees who will receive a medical placement health review will be evaluated for:
 - a) Prior TB history and any previous therapy for tuberculosis.
 - b) Prior TST placement (to include dates of the most recent negative or positive TST and any known prior TST conversion).
 - c) Prior preventative therapy for tuberculosis (if any) to include dates, types of treatment and results of prior chest radiographs.
- 2) Follow-up and treatment of all employees with suspected tuberculosis (infection or disease):
 - a) CDC guidelines for the treatment of tuberculosis will be the basis for all therapeutic decisions after evaluation by an EOHW physician.

- b) Evaluation of all employees with suspected or known active tuberculosis is the responsibility of EOHW. Such employees will be relieved from work until active disease is ruled out by appropriate medical and microbiological studies. Grounds for removing any employee from work may include but are not limited to the development of signs or symptoms suggestive of active tuberculosis and/or radiographic changes consistent with active pulmonary tuberculosis. All employees with confirmed active tuberculosis will be reported to DCPH to facilitate evaluation of the employee's other contacts outside Duke, especially children.
- 3) Follow-up of all employees with potential exposures (see Section VI below).
- 4) Periodic screening of employees (see Section V below).
- 5) Implement the Respiratory Protection Program Policy for TB.

G) Duke Student Health Service

- 1) All Duke medical students and other allied health students will have a TST within 12 months prior to matriculation.
- 2) All Duke medical students and other allied health students are required to have annual TST.
- 3) All students who have a documented or suspected exposure to a patient with infectious tuberculosis will be evaluated at the Student Health Center using the same criteria as for Duke employees (see Section VI).
- 4) Students have six weeks following notification of the need for post-exposure tuberculin testing in which to record a current tuberculin test result with Duke Student Health. A second test will be required approximately three months after exposure. Noncompliant students will be restricted from clinical rotations.
- 5) Students who perform patient care activities and travel to countries or areas within the U.S. designated by CDC/WHO as high hazard/high burden for TB must have a recorded tuberculin test result with Duke Student Health within a time frame of greater than three months and not more than six months after returning to Durham. Noncompliant students will be restricted from clinical rotations.

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

H. The Clinical Microbiology Laboratory (CMB) (Appendix C)

- 1) Specimens will be accepted for *M. tuberculosis* isolation, identification, and susceptibility testing in the CMB Laboratory, 108 CARL building. Routine AFB smears and cultures will be done weekdays. The CMB Laboratory will report all positive *M. tuberculosis* test results to Infection Control or the PHE (see Appendix C) and forward all culture results to the NC Department of Health and Human Services, (Form DHHS 3005 [8/99]).
- 2) CMB will provide an annual report to Biological Safety summarizing all isolates of *M. tuberculosis* and their susceptibilities.

I. Anatomic Pathology

- 1) The Department of Pathology (including Autopsy, Cytopathology and Surgical Pathology) will notify Infection Control or the PHE when specimens, tissues or organs are found on pathological examination to exhibit findings consistent with an infectious form of tuberculosis. These reports will be made by phone and in writing to Infection Control or to the PHE. Whenever possible samples of these suspicious specimens will be sent to the Clinical Microbiology Laboratory for AFB culture to confirm disease and all for epidemiological investigations by Infection Control or the PHE, and the North Carolina public health system.
- 2) The Autopsy Service will notify Infection Control or the PHE when thick-walled cavitory lesions of the lung containing caseous necrosis are found to communicate with an open bronchus or when a granulomatous laryngeal lesion of unknown etiology is encountered.
- 3) The Pathology Department will notify Infection Control or the PHE when microscopic examination of any surgical or autopsy specimen discloses any form of tuberculosis.
- 4) The Surgical Pathology Department will notify Infection Control or the PHE when they encounter any necrotizing caseous granulomatous lesion with or without a cavitory component which has findings consistent with an infectious form of tuberculosis. All

procedures that have the potential of producing aerosols on specimens from patients known to have active multi-drug resistant tuberculosis are to be performed within a certified biological safety cabinet using appropriate biosafety precautions for the specific process/procedure in accordance with CDC/NIH guidelines.

- 5) The Cytopathology Unit will notify Infection Control or the PHE of any AFB smear-positive results.

J) Human Resources

All contract workers for Duke Hospital will provide documentation of a TST within the past year.

V) TUBERCULIN SKIN TESTING

A) Tuberculin skin testing is used for new employee screening, for periodic employee surveillance (see Section XIII A), and after potential employee exposures to TB. The test will be placed using the Mantoux method.

B) A TST will be placed on all new employees who receive a medical placement health review unless they have one of the following conditions:

- 1) History of a prior TST reaction 10 mm in diameter or greater. The employee must provide documentation of a previous positive test or the employee will be tested again by EOHW.
- 2) History of prior treatment for tuberculosis infection or disease.
- 3) Allergy to TST reagents.
- 4) Currently receiving anti-tuberculosis therapy.
- 5) Documented negative test within the last 90 days.

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

D) A standard TST will employ 5 units of tuberculin and will be read 48-72 hours after placement by personnel from EOHW or other licensed HCWs (i.e., MD, RN, PA, or NP).

E) Employees who are 55 years or older, persons from high prevalence areas, or have a history of BCG vaccine but no documentation of a positive tuberculin status and who have not had a TST within the last year will be tested and if negative will have a repeat test after a minimum of two weeks. Thereafter, such individuals will have routine tuberculin skin testing.

F) All TST reactions meeting the following criteria will be classified as positive:

1) **Greater than or equal to 5 mm of induration if:**

- a) The employee is a close recent contact of a patient with infectious tuberculosis.
- b) Their screening X-ray shows fibrotic changes thought to be consistent with old, healed tuberculosis infection.
- c) The employee has known HIV infection.

2) **Greater than 10 mm induration** if one or more of the following are present:

- a) Other medical risk factors known to substantially increase the risk of tuberculosis disease once infection has occurred (see Appendix B).
- b) The employee is a foreign-born person from a high prevalence country such as Asia, Africa, Latin America, or countries that were in the former Soviet Union.
- c) The employee has had recent residence in a high prevalence area for tuberculosis (such as New York City).
- d) The employee is from a medically underserved population.
- e) Recent IV drug abuse has occurred or is suspected.
- f) The employee has regular employment in a patient area or other high hazard area.

3) **Greater than 15 mm induration** if the employee is not in category 1 or 2.

G) Employees who are prior BCG vaccine recipients will be evaluated and tested in the same manner as other employees. If their TST is

positive, they will be evaluated by the same criteria used for other employees (i.e., their BCG status will not affect their evaluation or follow-up).

H) Pregnancy is not a contraindication for tuberculin skin testing. The same guidelines used for non-pregnant employees will be utilized to test and evaluate pregnant employees with two exceptions:

- 1) Pregnant employees infected with *M. tuberculosis* will be informed of the possibility that infection can progress more rapidly during pregnancy.
- 2) Pregnant employees who meet current guidelines for prophylactic therapy or treatment of active disease will be handled on an individual basis in conjunction with their primary physician. [Note: both INH and Rifampin are considered safe for use in pregnancy in general, preventative therapy and treatment of active disease are considered safe and appropriate in pregnant women].

VI) EXPOSURE INVESTIGATION

An exposure will be defined as contact with a patient or non-human primate with infectious tuberculosis in inadequate respiratory isolation.

A) Infection Control or the PHE will notify OESO when a patient with infectious tuberculosis has been admitted to the hospital or seen in the clinics in whom isolation was inadequate. It will be the responsibility of EOHW and OESO to follow up on possible employee exposures.

B) Records of patients from whom *M. tuberculosis* is isolated will be reviewed to collect names of potentially exposed employees and estimate cumulative potential exposure time for these employees. OESO will notify Department Managers of all such exposures; Infection Control or the PHE will notify the physicians of exposed patients. It will be the joint responsibility of OESO and Department Managers to prepare a list of exposed employees for subsequent follow-up and evaluation. It will be the responsibility of individual physicians to notify exposed patients and arrange for their follow-up and evaluation.

C) Post-exposure testing will focus on those staff that constitute a “first circle” of exposure such that the maximum number of staff tested in most cases will be less than 20. Any conversions within this first group will result in testing of all those exposed. In addition community conversion data on all cases will be aggressively pursued to assist with the decision on the depth of testing. Exposed staff will be asked to define their estimated cumulative hours of exposure, if needed. All such evaluations

will include the documentation of the circumstances of the exposure, the level and duration of the exposure, the presence or absence of signs and/or symptoms of active tuberculosis in the source patient. Those chosen for “first circle” testing will be those with the most exposure time.

D) Employees to be evaluated will be notified and evaluated by EOHW. All such evaluations will include the presence or absence of signs and/or symptoms of active tuberculosis in the exposed employee, prior TST status of the employee and the subsequent risk of tuberculosis infection and/or disease in the employee. Once notified, it is expected that the employee will have Tuberculin Skin testing. Employees have three weeks post notification to respond or their department director or chairperson will be notified. Any employee who has not had tuberculin test results recorded in EOHW within six weeks of the notification will be restricted from further work at Duke.

E) In the event of a known exposure to tuberculosis Infection Control or the PHE will notify OESO who will, in turn, notify the Department Managers and Nurse Managers at the location the TB exposure was known to have occurred. After consultation with department heads, supervisors, nurses, OESO will notify EOHW of exposed employees to be evaluated.

F) In addition OESO will notify outside contractors if any of their employees have been exposed to tuberculosis. It will be the responsibility of these outside contractors to contact such exposed individuals and arrange for their appropriate evaluation and follow-up.

G) Exposed employees will have their TST status established following a significant exposure. If the employee has not had a TST placed within the last three months prior to the exposure, a baseline TST will be placed at that time. When such tests are negative, a follow-up TST should be repeated 10-14 weeks later.

H) In all instances of nosocomial transmission of tuberculosis an attempt will be made to identify the source. When a source patient is identified, drug susceptibility testing will be performed and the results of these studies will be shared with all physicians who evaluate and treat exposed or infected contacts.

I) When an employee returns from providing patient care in an area that is high risk for TB the employee will undergo evaluation by EOHW when returning to work at Duke.

VII) MANAGEMENT OF PATIENTS WITH KNOWN OR SUSPECTED TUBERCULOSIS

A) Recognition of Patients with Potential Tuberculosis Infection

- 1) Diagnosis of tuberculosis should be considered in any patient with unexplained prolonged cough or complaints such as hemoptysis, night sweats, weight loss, or fever in whom an alternate diagnosis has not been established or thought to be highly likely. All patients with suspected tuberculosis should be placed in Airborne Isolation in a designated isolation room by their primary health care givers until active infectious tuberculosis is excluded. It is the responsibility of the physicians and nurses caring for individual patients with known or suspected tuberculosis to initiate isolation. Questions concerning the medical or epidemiological rationale for continuing such isolation should be forwarded to Infection Control or the PHE.
- 2) Appropriate diagnostic studies should be conducted on all patients with suspected tuberculosis. These studies may include tuberculin skin testing; collection of sputum, smears, and cultures; and chest radiography. In selected instances, bronchoscopy, the induction of sputum for microbiologic studies, nasogastric aspirations (for pediatric patients), and/or bone marrow biopsy may be undertaken.
- 3) When patients with previously diagnosed tuberculosis are admitted to Duke before there is microbiologic and/or clinical confirmation of cure, Airborne Isolation must be utilized pending further assessment and evaluation of their infectiousness. Questions concerning prior TB treatment at the patient's county health department should be directed to Infection Control or the PHE at 684-5457 (pager 970-9721).

B) Inpatient Management of Patients

- 1) All patients with known or suspected pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain *M. tuberculosis*) will be placed in Airborne Isolation in an appropriately ventilated isolation room (described in detail in Section VIII A) and Infection Control or the PHE will be notified. This isolation will include admission to a designated isolation room whenever possible (Appendix D) and the wearing of proper protective respiratory devices by all persons entering the patient's room. Proper protective respiratory devices are described in detail in Appendix F and include N95 respirator masks for those employees who are fit-tested by EOHW and Powered Air Purifying Respirators

(PAPRs) for those who are not fit-tested. See Appendix F for instructions on ordering PAPRs from Equipment Distribution. Bacterial/viral filters will be used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.

- 2) Visitors are to wear N95 respirator masks while in the patient's room. The patient's primary nurse is responsible for providing the visitors with instructions on how to wear the N95 respirator masks and how to perform a user seal check before allowing the visitors to enter the patient's room. Visitors with beards, mustaches, or are unable to achieve a tight seal during the seal check should be shown how to wear a PAPR.
- 3) If a designated isolation room is not available (i.e., all are being used for Airborne Isolation), 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 isolation room for the area they are in (these are the back-up isolation rooms listed in Appendix D that are located throughout the hospital). The remainder of the instructions in Section VII B 1 will be followed.
- 4) If a TB isolation room (designated or back-up) is not available or if the patient is in an area that lacks isolation rooms (e.g., Radiology) then a portable high-efficiency particulate air filter (HEPA) will be placed in the patient room (refer to Section IX) and the remainder of the instructions in Section VII B 1 will be followed. 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 the Equipment Distribution Department through DHIS or by calling the Service Response Center at 681-2727.
- 5) Airborne Isolation is required for:
 - a) Patients presenting with signs and symptoms of TB, with particular importance placed on the presence of a persistent cough (see Appendix B). In patients with normal immune systems the chest x-ray is often the most valuable tool used to raise suspicion for TB. Persons with impaired immune systems often do not have chest x-rays suggestive of TB even though they may have the disease. Also, if a patient that presents with only one or two of these signs and symptoms of TB and belongs

to one of the groups that are at high-risk for TB, then suspicion for active TB should be raised (see Appendix B).

- b) Patients with **sputum smears positive for AFB** in whom an alternate diagnosis has not been established or strongly expected. If *M. tuberculosis* complex is identified, the drug susceptibility pattern of that isolate must be determined before airborne isolation is discontinued regardless of any subsequent smear results.
 - c) Patients with **confirmed** active pulmonary or laryngeal tuberculosis who have **sputum smears positive for AFB.** **These patients are considered infectious and must be kept on Airborne Isolation until:**
 - ❖ They have three consecutive sputum smears collected at least eight hours apart which are negative, one of which should be an early morning specimen; and
 - ❖ They have been compliant on tuberculosis medications to which the organism is judged to be susceptible; and
 - ❖ There is evidence of clinical response to tuberculosis treatment.
 - d) Airborne Isolation is required for any patient with active multi-drug resistant tuberculosis (MDR-TB).
 - e) **A physician order is required to discontinue Airborne Isolation, along with the appropriately documented rationale for the decision.**
- 6) Airborne Isolation is **not** required:
- a) For patients with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative once they have been started on tuberculosis treatment.
 - b) For patients admitted with a diagnosis of “rule out tuberculosis” if that diagnosis is considered an unlikely but theoretically possible diagnosis (i.e., patients who are currently not coughing and who simultaneously do not have cavitory lung lesions suggestive of tuberculosis).
- 7) Infection Control or the PHE must be notified when patients are placed on Airborne Isolation for tuberculosis. All such patients will be individually evaluated by personnel from Infection Control or the PHE to ensure the use of proper precautions. Infection Control or the PHE will in turn notify OESO of the presence of an isolated

patient. OESO will assure that appropriate respiratory protection is available and will monitor ventilation status daily.

- 8) Airborne Isolation may be initiated by attending physicians, consulting physicians, triage nurses, inpatient nurses, physician assistants, nurse practitioners, the PHE, or Infection Control personnel. (Isolation 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 isolation.) In the event that a dispute occurs over the need for isolation, the Chairman of the HICC has the responsibility to review the circumstances and decide upon the need for isolation. (Refer to Section IV C 2)
- 9) All patients placed in Airborne Isolation will be instructed by the patient's medical and nursing staff on the need to adhere to isolation policies and to cover their mouth and nose with tissues when coughing and sneezing. Patients are to stay in their isolation rooms until tuberculosis has been ruled out. (See Section C, below for the criteria required to discontinue isolation.) The only time a patient may leave their room is if a diagnostic procedure must be performed outside of the isolation room. Infection Control or the PHE can be contacted for advice on this issue. Patients who refuse to adhere to Airborne Isolation will be reported to the Durham County Health Department. (Appendix A) Legal action may be taken to enforce appropriate Airborne Isolation precautions when requested by the attending physician, the PHE, or Infection Control. The Duke Public Safety Office will assist local law enforcement as needed in enforcing court-ordered isolation.
- 10) In the event that a patient with known or suspected tuberculosis must be transported to another area within the hospital for any reason, these patients 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 isolation room while the patient is wearing a mask. In instances where diagnostic testing must be done outside the isolation 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 Airborne Isolation. A procedure request form should indicate the need for Airborne Isolation.

C) Discontinuation of Isolation

- 1) Airborne Isolation may be discontinued:
 - a) In instances where an alternate diagnosis has not been established, tuberculosis is considered ruled out when:
 - ❖ the patient has three consecutive sputum smears collected at least eight hours apart which are negative, one of which should be an early morning specimen;
 - ❖ the patient has been compliant on tuberculosis medications to which the organism is judged to be susceptible; and
 - ❖ there is evidence of clinical response to tuberculosis treatment.
 - b) The patient does not have multi-drug resistant tuberculosis.
 - c) Persons with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative do not require airborne isolation once they have been started on tuberculosis treatment.
 - d) Patients with confirmed pulmonary tuberculosis who are smear positive at any point in their hospitalization must stay on airborne isolation until the isolate's drug susceptibility pattern is known.
 - e) For patients with suspected tuberculosis when an alternate diagnosis has been either confirmed or is thought highly probable by the attending physician, (e.g., patients with a past history of a fungal pulmonary disease, or patients with a known history of infection with nontuberculosis mycobacteria who may have presented with positive AFB smears).
 - f) Airborne Isolation may be discontinued for patients with soft tissue or open draining lesions when the wound is either no longer draining or the draining material no longer contains acid-fast material on at least three occasions (if the patient is concurrently on effective anti-tuberculosis chemotherapy).
- 2) Under special circumstances, Airborne Isolation may be discontinued at the discretion of the Chairman of the HICC.

D) Outpatient Management of Patients (Refer to Appendix G for Clinic Flowcharts)

1) For all clinics:

- a) Notify Infection Control or the PHE when patients are placed on Airborne Isolation for known or suspected tuberculosis in the clinics. Infection Control, the PHE, and Biological Safety will provide advice concerning the use of proper precautions and will ensure that confirmed employee exposures are evaluated.
- b) If a patient with known or suspected **infectious** pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain or are suspected of containing *M. tuberculosis*) must be seen in an outpatient clinic and the visit cannot be rescheduled to a time when the patient is no longer considered infectious, the clinic should be notified prior to the patient's arrival.
- c) The patient should be instructed to wear a surgical mask when entering the building where the clinic is located - and clinic staff should place the patient directly into the exam or procedure room and close the door – the patient should not spend any time in a waiting room with other patients or visitors. These precautions should also be taken with coughing children with known or suspected tuberculosis. If the patient can wear a surgical mask during their entire visit employees do not need to take respiratory precautions.
- d) If the clinic is not equipped to handle TB patients (employees are not fit-tested and ventilation is not adequate) and the patient cannot wear a surgical mask during the entire visit, consider referring the patient to a clinic that is equipped to handle TB patients, an Emergency Department, or the health department in the patient's county of residence.
- e) Patients are no longer considered infectious if they meet **all** three criteria that follow:
 - ❖ They have three consecutive sputum smears collected at least eight hours apart which are negative (with one specimen preferably an early morning specimen when the yield of AFB is greater.
 - ❖ They have been compliant on tuberculosis medications to which the organism is judged to be susceptible.
 - ❖ There is evidence of clinical response to tuberculosis treatment.

- f) Note: Persons with suspected or known active pulmonary or laryngeal tuberculosis who are initially sputum smear negative do not require respiratory isolation once they have been started on tuberculosis treatment.
- g) Before discontinuing Airborne Isolation 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 (contact Infection Control or the PHE).

2) In Duke Clinic, if the patient cannot wear a surgical mask for the entire visit:

- a) If an appropriately ventilated isolation room is not available (described in detail in Section VIII A), a portable HEPA should be placed in the exam or procedure room where the patient will be seen (refer to Section IX). 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 from the Equipment Distribution Department through DHIS or by calling the Service Response Center in Duke Hospital at 681-2727.
- 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 Appendix F and include N95 respirator masks for those employees who are fit-tested by EOHW and Powered Air Purifying Respirators (PAPRs) for those who are not fit-tested. If PAPRs are needed in an area where they are not stocked or if additional PAPRs are needed they can be obtained through DHIS or by calling the Equipment Distribution Department at 681-2727. The disposable head coverings are ordered from Material Services through SAP # 330895. In a medical emergency with an unmasked patient an N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.

3) For off-site clinics:

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

- b) If the suspicion of infectious TB disease is discovered during a clinic visit place a surgical mask on the patient as soon as possible. Contact a clinic equipped to handle TB patients (fit-tested employees and adequate ventilation), a local Emergency Department, or the health department in the patient's county of residence and make plans to refer the patient. Keep the patient in an exam room with the door closed until the patient can be referred. In a medical emergency with an unmasked patient an N95 respirator mask is acceptable temporary protection whether the employee is fit-tested or not.

4) Emergency Medical Service:

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

E) Management of Patients in the Operating Room

- 1) Because the current Operating Room 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 is 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 60 minutes. 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](#)).
- 3) The case should be scheduled in a room with an adjoining induction room (i.e., double door access) and should be scheduled as the last case of the day.

- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) All employees entering the room or enclosed area must wear N95 respirator masks.
- 6) During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended ventilation standards for TB isolation rooms (listed in Appendix D) or remain in the Operating Room.
- 7) The following ICU level isolation rooms are on a designated TB unit: 8201 and 8216. If a patient requires Airborne Isolation attempts must be made to first place them in one of these rooms. *If these rooms are already occupied by patients on Airborne Isolation, or if medically the patient requires the specialized care of one of the other intensive care units then one of the following isolation rooms may be used: 3201, 3216, 4201, 4216, 5610 (pediatrics only), 7201, and 7216.* Patients on Airborne Isolation have priority for these rooms.
- 8) The approved N95 respirator mask is worn at all times by anyone entering the patient's isolation room. Powered Air Purifying Respirators (PAPRs) may be used outside of the operating suites.
- 9) In cases of known multi-drug resistant tuberculosis that require surgery, contact Biological Safety (684-8822) for coordination of additional engineering controls to be implemented by the Engineering and Operations HVAC division. Also contact EOHW to arrange for N95 respirator fit-testing for those employees working within the sterile field. The details for this protocol can be found in the Operating Room Safety Manual.

VIII) VENTILATION CONTROLS

A) Isolation Rooms – Inpatient (listed in Appendix D)

Patients with known or suspected tuberculosis will be placed in designated isolation rooms. The doors for these isolation rooms must remain closed, and entrance is allowed only through anteroom doors. Allow approximately 30 to 45 minutes after a known or rule out tuberculosis patient leaves an isolation room before entering without respiratory protection. During this time the doors should remain closed as much as possible. The ventilation time is based on the room size and the air changes per hour and varies from room to room. Such designated isolation 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. OESO will monitor this negative airflow periodically using smoke tubes. In addition, a list of rooms that provide appropriate ventilation (Appendix D) will be maintained by OESO and provided to Bed Control, departmental managers, nurse managers, the PHE, and Infection Control. It is the responsibility of OESO to maintain records on the testing and utilization of these isolation rooms and to notify the Infection Control Committee of deficiencies and inadequacies of ventilation controls.

B) TB 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 isolation rooms (Section V B). If such rooms are not available, supplemental control devices such as isolation booths or portable HEPAs must be employed (refer to Section IX for information on portable HEPAs). 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](#)). After completion of cough-inducing procedures, patients with known or suspected tuberculosis must remain in the isolation booth or isolation room until coughing subsides and be instructed to use tissues to cover their mouth and nose when coughing. Cough-inducing procedures other than inductions to collect sputum samples for TB evaluation should not be performed on patients with active tuberculosis unless absolutely necessary. Employees must wear respiratory protection while cough-inducing procedures are performed on patients with known or suspected tuberculosis (see Appendix F). Patients with known or suspected tuberculosis who are recovering from sedatives or anesthesia following procedures such as bronchoscopy must be monitored in a separate isolation room. After the patient leaves the treatment or procedure room, the room air should be given time to turn over prior to the next patient being placed in the room. One hour should be adequate for most treatment rooms. During this time, the door should remain closed, employees should wear appropriate respiratory protection when entering the room and the portable HEPA should be left running during this time.

2) Aerosol-Generating Procedures:

- a) Autopsy rooms should meet the criteria for isolation rooms in Section V B. They must be at negative pressure with respect to adjacent areas and the room air should be exhausted directly to the outside of the building because infectious aerosols are likely to be present. Respiratory protection should be worn by personnel while performing autopsies on deceased persons who may have had TB at the time of death (see Appendix F).
- b) Laboratory workers handling specimens potentially containing TB organisms must adhere to the CDC/NIH Guidelines. For example, procedures causing aerosolization of TB must be performed within a Biological Safety cabinet (BSC). Laboratories without BSCs should be evaluated by Biological Safety for alternative control measures.

IX) **PORTABLE HIGH-EFFICIENCY PARTICULATE FILTER UNITS**

Portable high-efficiency particulate air (HEPA) filter units will be used in the control of tuberculosis in known or suspected cases of infectious tuberculosis who are hospitalized in the Labor and Delivery areas, the Operating Room, the Ambulatory Care areas, the Outpatient Clinics, the Radiology departments, and the Interventional Cardiac Catheterization Laboratory **or any area where such patients may be housed and recommended ventilation is not available**. 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 (extra units are available through DHIS or by calling Equipment Distribution at 681-2727). 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.

X) **RESPIRATORY PROTECTION (also see Appendix F)**

A) All employees entering an enclosed area where a patient or non-human primate who has known or suspected tuberculosis must wear an appropriate respiratory protection device.

B) Appropriate respiratory protection is worn by all personnel performing or assisting in cough inducing procedures such as bronchoscopy or the delivery of aerosolized pentamidine treatments on patients with known or suspected TB. Appropriate respiratory protection must also be worn by personnel mixing or administering BCG outside of a Biological Safety cabinet.

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

D) The Respiratory Protection Program for TB is administered by EOHW. (Appendix F)

XI) DISCHARGE PLANNING

A) Criteria for Discharge

- 1) Unless discharged to an institution with tuberculosis isolation facilities or home with the restrictions noted in #3, discharge of institutionalized patients with active TB requires a minimum of two criteria: initial therapy with a minimum of four anti-tuberculosis drugs until susceptibility test results are known, and at least three negative AFB smears collected at least eight hours apart with one specimen preferably an early morning specimen.
- 2) Contact the health department in the patient's county of residence no less than 48 hours before a patient with active tuberculosis is discharged (see Appendix A). The PHE or Infection Control will provide assistance in contacting the patient's local health department ensuring that the health department is provided with the specific information required prior to discharge. Refer to guidelines found in the [Infection Control policies and procedures](#) on the Duke Intranet.
- 3) Patients who may be infectious at the time of discharge should only be discharged to other facilities with tuberculosis isolation capabilities or to home. They should not be discharged to home while considered infectious if there are persons in the household who are at high risk of acquiring active tuberculosis (such as children less than five years of age or persons infected with HIV or others who are severely immunocompromised).

- 4) It is the responsibility of the attending physician to write discharge orders that adhere to provisions described above. These criteria can only be altered at the discretion of the Chairman of the HICC in corroboration with the patient's personal physician and/or the local health department.

XII) EDUCATION

- A) Responsibility for education of staff concerning tuberculosis control policies, procedures and their implementation will be the joint responsibilities of Infection Control, the PHE, and OESO.
- B) All Duke medical students and allied health students will receive instruction on TB control measures before rotations in patient care or CMB.
- C) All employees whose jobs involve a potential for exposure to tuberculosis will receive education that is specific for their work responsibilities. Such training is conducted at the time of employment by OESO and annually thereafter. Although the level and detail of this training may vary according to job description, the following elements are included in orientation training for employees with exposure determination ratings of Airborne Pathogens 1- 4 and Animal Contact 2:
 - 1) Basic concepts of the transmission, pathogenesis and diagnosis of tuberculosis (including the difference between tuberculosis infection and active disease due to tuberculosis, potential signs and symptoms of tuberculosis and the possibility of late reactivation of asymptomatic tuberculosis infection).
 - 2) The risk of occupational exposure to tuberculosis, the rationale for isolation and situations that increase the risk of exposure to tuberculosis, and the steps to be taken if exposure occurs.
 - 3) The hierarchy of control measures designed to prevent transmission of tuberculosis outlined in this plan and a summary of policies and procedures related to this goal. Area-specific control measures will be provided to personnel who work in areas with special or unique risks.
 - 4) The rationale and necessity of annual tuberculin skin testing in high-risk areas, the potential significance of a positive TST and their responsibility and obligation to participate in annual tuberculin skin testing programs.

D) All records related to education and training of employees will be stored in a computer database maintained by OESO. Statistical summaries of training by exposure determination group will be provided periodically to the HICC and the Safety Committee by OESO.

XIII) PERIODIC EMPLOYEE SURVEILLANCE:

A) Employees with negative tuberculin test:

- 1) Personnel with exposure determinations of Airborne Pathogens 4 and/or Animal Contact 2 will be tested annually.
- 2) Routine surveillance testing for all employees with significant contact with patients will be conducted on a 13-month cycle rather than 12 months. This is designed to reduce the bolus effect caused by the high rate of hiring which occurs between the end of May and mid-July.

B) Employees with prior positive tuberculin reactions or those who cannot take the TST for other medical reasons will be required to complete an annual questionnaire in place of the annual TST that includes specific questions concerning the absence or presence of symptoms suggestive of active tuberculosis or other risk conditions. (Appendix B). This includes employees with patient contact in high-risk areas or animal care personnel working with non-human primates.

C) Employees with positive tuberculin skin tests who have completed a full course of preventative therapy with INH require no follow-up.

D) Employees who are new converters:

- 1) All employees with documented recent TST conversion will be counseled by EOHW and have the following tests:
 - a) Chest x-ray.
 - b) Clinical assessment that includes evaluation of the patient's health history, including high risk associated disease(s) (Appendix B), possible source of conversion and whether the conversion was likely or possibly related to their occupation.
 - c) HIV testing.
- 2) INH prophylaxis (or other alternate therapies) will be recommended for all recent tuberculin converters consistent with current

recommendations of the CDC/USPHS and the Tuberculosis Advisory Group.

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

E) Treatment of employees with active tuberculosis:

- 1) Anti-tuberculous therapy based on current CDC recommendations will be advised for all employees with active tuberculosis.
- 2) Employees will be relieved from work activities until EOHW authorizes their return. The local health department will be notified and consulted.
- 3) 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.

XIV) APPENDICES

Appendix A: Durham County & North Carolina Public Health Services

A) Durham County Health Department (DCHD)

Tuberculosis is a reportable disease in North Carolina. NC General Statute (130A-135) requires licensed physicians to report cases and suspected cases of reportable communicable diseases and conditions in persons who have consulted them professionally. **Physicians (or Infection Control/PHE @ Duke) will forward case reports to the health department of the patient's county of residence** who will then forward them to the Epidemiology Division, Department of Health and Human Services (DHHS) P. O. Box 27687, Raleigh, NC 27611-7687. **Tuberculosis should be reported within 24 hours by phone and card (DHHS 2124).**

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

- 1) Follow-up of all contacts of Durham County cases and collaboration with other counties as needed.
- 2) Directly observed treatment for active cases.
- 3) Clinic services for patients discharged with *M. tuberculosis* (nursing, chest x-ray, laboratory, pharmacy, nutrition, and health education).
- 4) **All tuberculosis medication** (*M. tuberculosis*) for prophylaxis or treatment.
- 5) Tuberculin skin testing for anyone.
- 6) Chest x-ray as indicated for anyone with a (+) TST.
- 7) *M. tuberculosis* evaluation of persons with a previous (+) TST and one negative chest x-ray.
- 8) Maintenance of a registry of patients with tuberculosis who reside in Durham County.
- 9) All Durham County residents' case reports are reported to NC DHHS.

B) 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 culture positive for *M. tuberculosis* should be reported within seven days of obtaining the result. The completed report is sent to: DHHS, Division of Epidemiology, Tuberculosis Branch, P.O. Box 27687, Raleigh, NC 27621-7687. (Appendix C)

C) Statutes of the State of North Carolina provide the following for TB control:

- 1) **Duty to pay:** outpatient treatment paid for by the patient's local health department.
- 2) **Public health powers to direct:** examination, outpatient care, in-home isolation, or hospitalization for a person with (or suspected) tuberculosis.
- 3) **Confidentiality:** Protection is provided to the individual, but release of information for statistical purposes, public health control measures, and to medical persons providing care for a patient is enabled.

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

Appendix B:

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)
[WHO: TB - Profiles of High-Burden Countries](#)
- Persons who are medically underserved
- Alcoholics / IV drug abusers
- Residents and employees of high-risk congregate settings (e.g., long-term care facilities, homeless shelters, or prisons)
- Persons with certain medical conditions which increase the risk of developing clinical tuberculosis once tuberculosis infection has occurred:
 - ❖ HIV infection (due to immunosuppression)
 - ❖ Silicosis
 - ❖ Abnormal chest radiograph showing fibrotic lesions
 - ❖ Diabetes mellitus
 - ❖ Prolonged corticosteroid therapy
 - ❖ Immunosuppressive therapy
 - ❖ Hematologic and reticula endothelial diseases
 - ❖ End-stage renal disease
 - ❖ Intestinal bypass
 - ❖ Post-gastrectomy
 - ❖ Chronic malabsorption syndromes
 - ❖ Carcinoma of the oral pharynx and upper gastrointestinal tract
 - ❖ Being 10% or more below the ideal body weight

Signs and Symptoms of Active TB

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

Appendix C: Clinical Microbiology (CMB) Laboratory

A) Service and Responsibilities

The CMB Laboratory of the Duke University Health System Clinical Laboratories, for the purposes of this Exposure Control Plan, will report all positive *M. tuberculosis* test results to the patient's physician and Infection Control or the PHE. In addition the CMB Laboratory will forward positive smear results and culture results positive for *M. tuberculosis* to the NC Department of Health and Human Services, Division of Epidemiology, Tuberculosis Control Branch (form DHHS 3005, 8/99). (Appendix A)

The Mycobacteriology Section of the CMB Laboratory is a College of American Pathologists (CAP) approved Extent III laboratory. All specimens received in the Mycobacteriology Section of the CMB Laboratory, 108 CARL Building, will be processed for detection and isolation of mycobacteria. All isolated mycobacteria are identified to the species level whenever possible. Susceptibility testing is performed on all isolates of *M. tuberculosis*. The following are the laboratory procedures and reporting policy of the CMB Laboratory.

B) Laboratory Procedures

1) Routine Procedure for Primary Isolation of Mycobacteria from Clinical Specimens:

Clinical specimens are processed by the Mycobacterial Growth Indicator Tube (MGIT) methodology using conventional preparation techniques as detailed in the CDC Manual, *Procedures for the Isolation and Identification of Mycobacteria*.

Sputum, gastric aspirates, tissues, and some other types of specimens must be liquefied (digested using a mucolytic agent) and decontaminated (selectively eliminating the bacteria) to enhance mycobacterial growth. N-acetyl-L-cysteine sodium hydroxide technique of Kubica and Dye is used at DUHS CMB. N-acetyl-L cysteine sodium hydroxide acts as the decontaminating agent. Sodium citrate stabilized the acetyl-cysteine with its ability to bind (by chelation) any heavy metal ions which may be present.

Other specimens such as sterile body fluids contain little organic material and if collected aseptically, do not require liquefaction or decontamination and may be directly inoculated onto the culture medium. If these specimens are received in large volumes, centrifugation aids in concentrating the mycobacteria present in the specimen.

All procedures; processing of specimens, smear preparation, media inoculation, subculturing, and sensitivity tests are performed in the Biological Safety cabinet in the Mycology/Mycobacteriology section using appropriate Level II or Level III biosafety precautions for the specific process/procedure, in accordance with CDC/NIH guidelines.

2) Routine Processing Time:

Specimens are processed daily Monday through Friday with the exception of holidays. Those specimens received before 9:30 am will be processed that same day. **Specimens received after 9:30 am are processed the following weekday.** Specimens received on evenings, late nights, Saturdays, Sundays, and holidays are refrigerated and processed the first available weekday.

3) Stat Acid-fast Smear:

A STAT direct smear will be done daily after 9:30 am and weekends or holidays on any patient for infection control purposes. Requests for a STAT AFB smear (**for *M. tuberculosis* only**) are to be referred to the Medical Microbiology Fellow (pager 970-8885). A technologist will perform a direct smear and stain on the unconcentrated specimen and report results by telephone or pager to the requesting physician. The smear result will be finalized after the concentrated procedure is performed on the next working weekday.

C) Reporting Positive Culture and Smear Results

1) Call the patient's physician and the PHE (668-4343 or 970-8853) or Infection Control (684-5457 or 970-9721) with:

- ❖ The first positive AFB smear result of each admission or encounter;
- ❖ the first positive identification of *Mycobacterium tuberculosis* complex (e.g., *Mycobacterium tuberculosis*, *Mycobacterium bovis*, and *Mycobacterium africanum*);
- ❖ susceptibility results on drug-resistant isolates; or
- ❖ a noted change in the susceptibility pattern of the patient's most recent isolate.

2) Supplementary Reporting

The Work Queue Sequence list is faxed daily to the PHE. This list includes all AFB culture requests on all patients (inpatients or outpatients) at DUHS.

Appendix D: Isolation Rooms

Isolation Rooms for Known and Suspect TB Patients

Designated TB Isolation Rooms

– Patients on Airborne Isolation should be placed in one of these rooms whenever possible, unless all these rooms are occupied by patients on Airborne Isolation or it is not medically appropriate to place the patient on one of these nursing units. Employees are fit-tested by Employee Health for the N95 respirator mask on these nursing units.

4332	7822	8101
5101 (Peds)	7831	8201
5131 (Peds)	7833	8216
	7834	8332

Back-up TB Isolation Rooms

– The list (below) is in order of preferred use. These rooms are to be used only if all possible designated TB isolation rooms are being used for patients on Airborne Isolation. Contact the PHE (668-4345 or 970-8853) or Infection Control (684-5457 or 970-9721) for approval. Employees not fit-tested by Employee Health for the N95 respirator mask must use the PAPR for respiratory protection.

1st Back-up Choice: 4101

2nd Back-up Choice: 6101 or 6332

-The following back-up isolation rooms are grouped together by medical specialty and would be used according to the medical needs of the patient:

<u>Med/Surg</u>	<u>Peds</u>	<u>NICU</u>	<u>PICU</u>	<u>L & D</u>	<u>Peds & OB</u>
2101	5332	5509	5610	5809	7732
2332		5510			

Other ICU's

3201	4201	7201	9201
3216	4216	7216	

Additional TB Back-up Isolation Rooms

(not to be used unless absolutely necessary due to the immunosuppressed patient population on these units)

3101	7101	9101
3332	7332	9332

High-Hazard / Cough-Inducing Procedure Rooms

(Always maintained in negative flow; air flows from least contaminated to most contaminated areas)

BUILDING	FLOOR / DEPT.	ROOMS
Duke Hospital *	0 / Bronchoscopy	0667, 0669, 0671
Children's Health Center *	3 / Peds Bronchoscopy	3907A, 3907B
Duke Clinic	2 / Clinic 2J, Infectious Disease Clinic	2338, 2340
Duke Clinic	3 / Autopsy	3222E, 3222F
CARL	1 / Clinical Microbiology Laboratory	111, 111A

* Room 0670 in Duke Hospital Bronchoscopy and room 3904H in the Periop. area of the Children's Health Center are routinely kept on positive pressure but can be converted to negative pressure by Engineering and Operations.

Appendix E: Annual TB Surveillance Groups 2009
(Safety Management System – Airborne Pathogens 4)

- ♦ Personnel assigned to work in the following areas (including PRMs, and ISRP):
 - N43
 - N51
 - N78
 - N81
 - N82
 - N83
 - Emergency Department
 - Life Flight (all EMS transport personnel)
 - Bronchoscopy (Adult and Pediatrics) – Part of “GI Diagnostic Services”
 - Infectious Disease Clinics – Adult (2J) and Peds
 - All Pulmonary Clinics - 2F/2G, off-site, and Peds
- ♦ Housestaff assigned to work in the following specialty groups/programs:
 - Emergency Department
 - Infectious Diseases
 - Pulmonary Medicine
 - Internal Medicine
 - Combined Medicine and Pediatrics
 - Psychiatry
- ♦ MD Faculty working in the following specialty groups/programs:
 - Emergency Department
 - Infectious Diseases
 - Pulmonary Medicine
 - Hospitalists
- ♦ Radiology patient-care providers (i.e., technologists, RNs, clinical tech. assistants)
- ♦ Respiratory Care Services patient-care providers and equipment handlers
- ♦ Clinical Microbiology Lab employees that work with AFB
- ♦ All Autopsy personnel (including MDs)
- ♦ IV Team
- ♦ Hospital-based ECG technicians (Heart Station)
- ♦ Physiologic Monitoring Cardiology technicians (part of Respiratory Care)
- ♦ Patient Advocates
- ♦ Interpreters (International Patient Center)
- ♦ Inpatient Phlebotomists (CLSS and Peds)
- ♦ Peds Clinical Lab Techs (only those performing inpatient phlebotomy)
- ♦ Employees that work with non-human primates
- ♦ Selected employees from the following groups, designated by their supervisor:
 - E&O HVAC employees
 - Laboratory staff that assist with bone marrow biopsies
 - Social Workers
 - Pastoral Care staff
 - EVS workers

Appendix F: Respiratory Protection Program Policy for TB

A. Introduction

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

In order to minimize the number of persons who must be entered into the Respiratory Protection Program, every effort will be made to cluster patients on Airborne Isolation onto the designated TB nursing units (4300, 5100, 7800, 8100, 8200, and 8300). Personnel included in the program will include, but are not limited to personnel in the following areas that may have direct contact with a patient on Airborne Isolation or the potential to be exposed to TB aerosols generated during high hazard procedures:

PERSONNEL REQUIRING N95 RESPIRATOR FIT-TESTING 2009
(Safety Management System – Airborne Pathogens 2)

- ♦ Patient-care providers (i.e., Nursing, PRMs, and ISRP) in the following areas:
 - 4300, 5100, 7800, 8100, 8200, 8300
 - Emergency Department (including unit coordinators)
 - Life Flight (all EMS transport personnel)
 - Infectious Disease Clinics - Adult (2J) and Peds
 - All Pulmonary Clinics – 2F/2G, off-site, and Peds
 - Bronchoscopy (Adult and Pediatrics), part of “GI Diagnostic Services”
- ♦ Housestaff assigned to work in the following specialty groups/programs:
 - Emergency Department
 - Infectious Disease
 - Pulmonary Medicine
 - Internal Medicine
 - Combined Medicine and Pediatrics
 - Psychiatry
- ♦ MD Faculty in the following specialty groups/programs:
 - Emergency Department
 - Infectious Diseases
 - Pulmonary Medicine
 - Selected MDs that work in Autopsy
 - Hospitalists
- ♦ Interpreters (International Patient Center)
- ♦ Designated employees in clinics with risk to aerosolized BCG: Urology (1G), Surgical Oncology (1A), and N. Duke St.
- ♦ Respiratory Care Services patient-care providers and equipment handlers
- ♦ Radiology patient-care providers in the following areas: (i.e., technologists, RNs, clinical tech. assistants)
 - Bone & Chest
 - Peds
 - CT
- ♦ Clinical Microbiology Laboratory AFB section employees performing procedures that have a high-risk for potential TB aerosol production (e.g., identification and susceptibility testing)
- ♦ Selected E&O HVAC employees (supervisor will designate)
- ♦ EVS employees working in areas designated as high-risk for potential TB aerosol exposure (supervisor will designate)

PERSONNEL DESIGNATED AS PAPR USERS 2009
(Safety Management System – Airborne Pathogens 3)

- ♦ Those who fail the N95 fit-test
- ♦ Those who have beards or other facial hair that interferes with the fit of the N95
- ♦ Autopsy Techs
- ♦ IV Team
- ♦ Hospital-based ECG technicians (Heart Station)
- ♦ Physiologic Monitoring Cardiology technicians (part of Resp. Care)
- ♦ Patient Advocates
- ♦ Inpatient Phlebotomists (CLSS and Peds)
- ♦ Selected Employees from the following groups, designated by their supervisor:
 - E&O HVAC employees
 - Laboratory staff that assist with bone marrow biopsies
 - Social Workers
 - Pastoral Care staff
 - EVS workers
- ♦ The following low-risk Radiology departments are also classified as PAPR users:
 - Mammography, Neurology Intervention, Ortho, GI, GU, Vascular Intervention, Pet Scan, Nuclear Med, Ultrasound & Fetal Diagnostic Center
 - Note: MRI Techs are not classified as needing respiratory protection

B. Respirators

- 1) The N95 respirator mask (N95):
 - 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.
 - b) Training on the proper use of N95's is required and is provided by Biological Safety. On-line training is available at [OESO's Safety Training Website](#). The module is called "Respirator Training for Airborne Pathogens".
 - c) The N95 will be available at all rooms or areas housing patients requiring Airborne Isolation. The N95 mask is approved for individual use only and cannot be shared between medical personnel working in the same area at different times. The mask cannot be used between patients. It can be 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).
 - d) It is important to note that these respirators are authorized for use in protecting employees from TB droplet nuclei. No other use is currently authorized.
 - e) N95 respirator masks can be ordered from Material Services through SAP:
 - [SAP #14173](#) Technol medium, orange, "duck-billed" mask
 - [SAP #14174](#) 3M medium, green, molded mask
 - [SAP #26378](#) 3M small, green, molded mask
 - f) **Note: Employees must wear the N95 respirator mask that they were fit-tested for.**
 - g) Priority fit-testing for the N95 is possible for small numbers of personnel that are providing direct care to a patient on Airborne Isolation on the non-fit-tested nursing units when the patient cannot be moved to a fit-tested nursing unit for medical reasons. Contact the PHE or Infection Control to have this arranged with EOHW.

- 2) PAPRs:
 - a) The PAPR will be used by all employees that are not fit-tested with the N95 mask including those employees with facial hair interfering with the sealing surface of the N95.
 - b) Training on the proper use of the PAPR is required and is provided by Biological Safety. On-line training for the PAPR is available at [OESO's Safety Training Website](#). The module is called "PAPR training – Airborne Pathogens". Biological Safety can be paged at 970-2780 for assistance in utilizing the PAPRs.
 - c) PAPRs are located in the Equipment Distribution Department and can be ordered through DHIS or by calling 681-2727. The disposable head coverings are ordered from Material Services through SAP (#330895).
- 3) **Note:** Anytime a person wearing a respirator experiences difficulty breathing, chest pain, or other symptoms they should exit the room and remove the respirator. If these symptoms are not relieved, then they should seek medical attention.

C. Respirator Approval Process

- 1) Medical clearance initially involves review of a screening questionnaire for medical conditions that may preclude respirator usage. Occasionally a person may need to be referred for further medical evaluation. Employees must be re-evaluated for medical clearance if their medical condition changes.
- 2) Training includes basic information regarding TB as taught through the initial orientation and annual update safety training programs, as well as information on the purpose, proper use, storage, handling, and limitations of the respiratory protective devices.
- 3) Fit-testing is required in accordance with OSHA regulations and involves matching a mask type and size to each individual's face and measuring leakage potential during use conditions. Personnel who have already been fit-tested at another institution within the last year do not need to be retested as long as they can provide adequate documentation and were fitted with one of the masks available at Duke.
- 4) Upon successful completion of medical clearance, annual training, and fit-testing (in accordance with OSHA regulations), each individual is approved to wear a specific respirator (type and size). Employees may only wear the respirator for which they have been approved. **Substitution by manufacturer, size, or model is not allowed.**

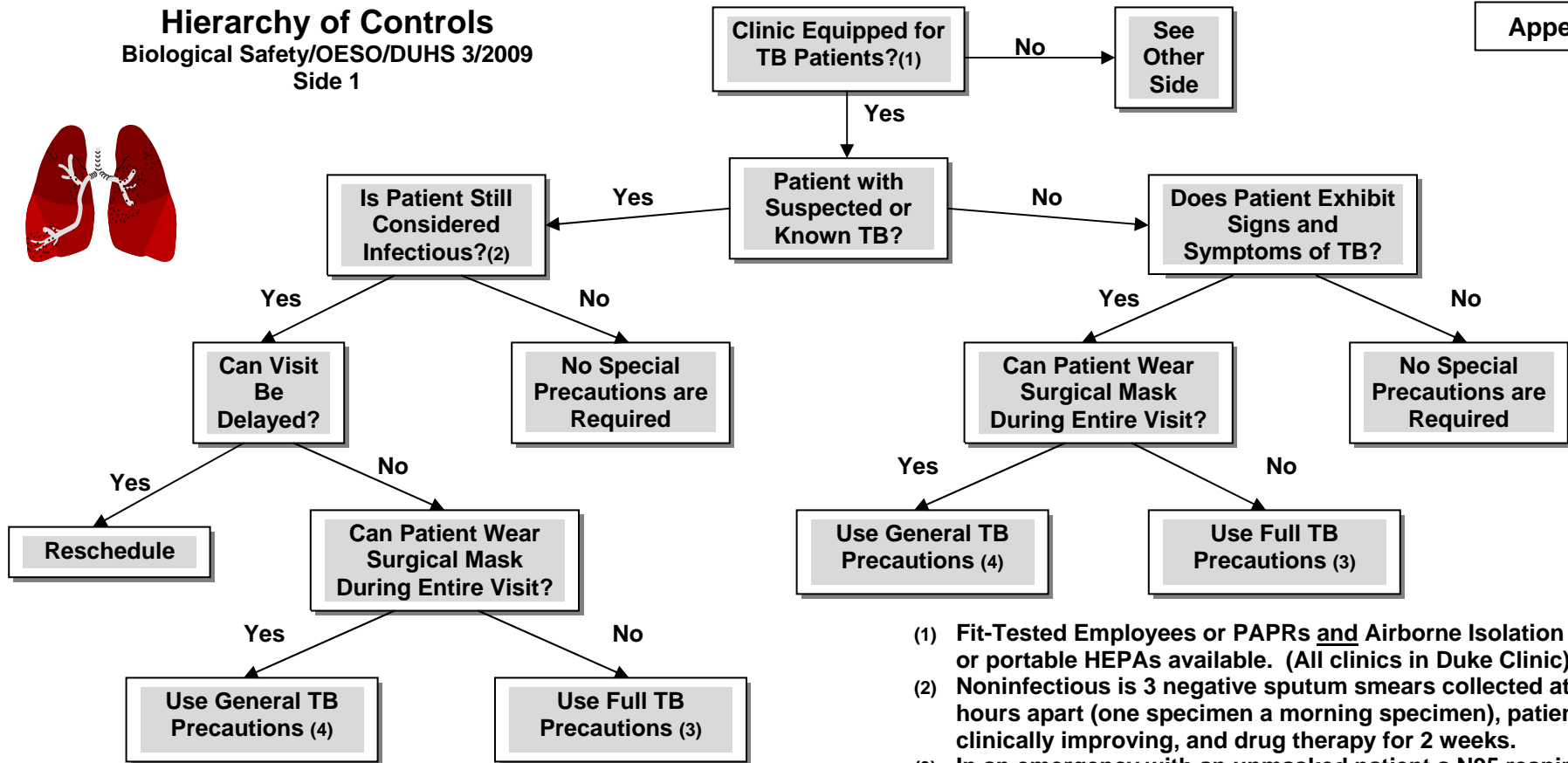
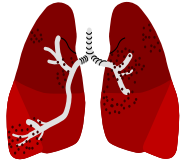
D. Monitoring

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

Clinic Visits from TB Patients – Hierarchy of Controls

Biological Safety/OESO/DUHS 3/2009
Side 1

Appendix G



- (1) Fit-Tested Employees or PAPRs and Airborne Isolation Rooms or portable HEPA's available. (All clinics in Duke Clinic)
- (2) Noninfectious is 3 negative sputum smears collected at least 8 hours apart (one specimen a morning specimen), patient is clinically improving, and drug therapy for 2 weeks.
- (3) In an emergency with an unmasked patient a N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.
- (4) If collecting sputum "Use Full TB Precautions".

Full TB Precautions in addition to General TB Precautions:

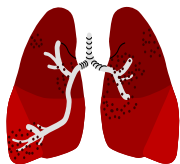
- ◆ The employee wears respiratory protection (a N95 respirator that they have been fit-tested for or a PAPR unit).
- ◆ Patient is placed in airborne isolation room or into exam room with portable HEPA unit (follow instructions posted on unit for use and for ventilation after the patient vacates).
- ◆ Place an Airborne Isolation sign on the door during patient visit and until the room has been ventilated.
- ◆ Ventilation time depends on the size of the room and the air changes per hour – contact Biological Safety for help in determining length of time.
- ◆ High-hazard procedures (e.g., sputum collection/induction, bronchoscopy) must be performed in a negative pressure airborne isolation room (bronchoscopy suites, ID clinic, or designated inpatient hospital rooms).

General TB Precautions:

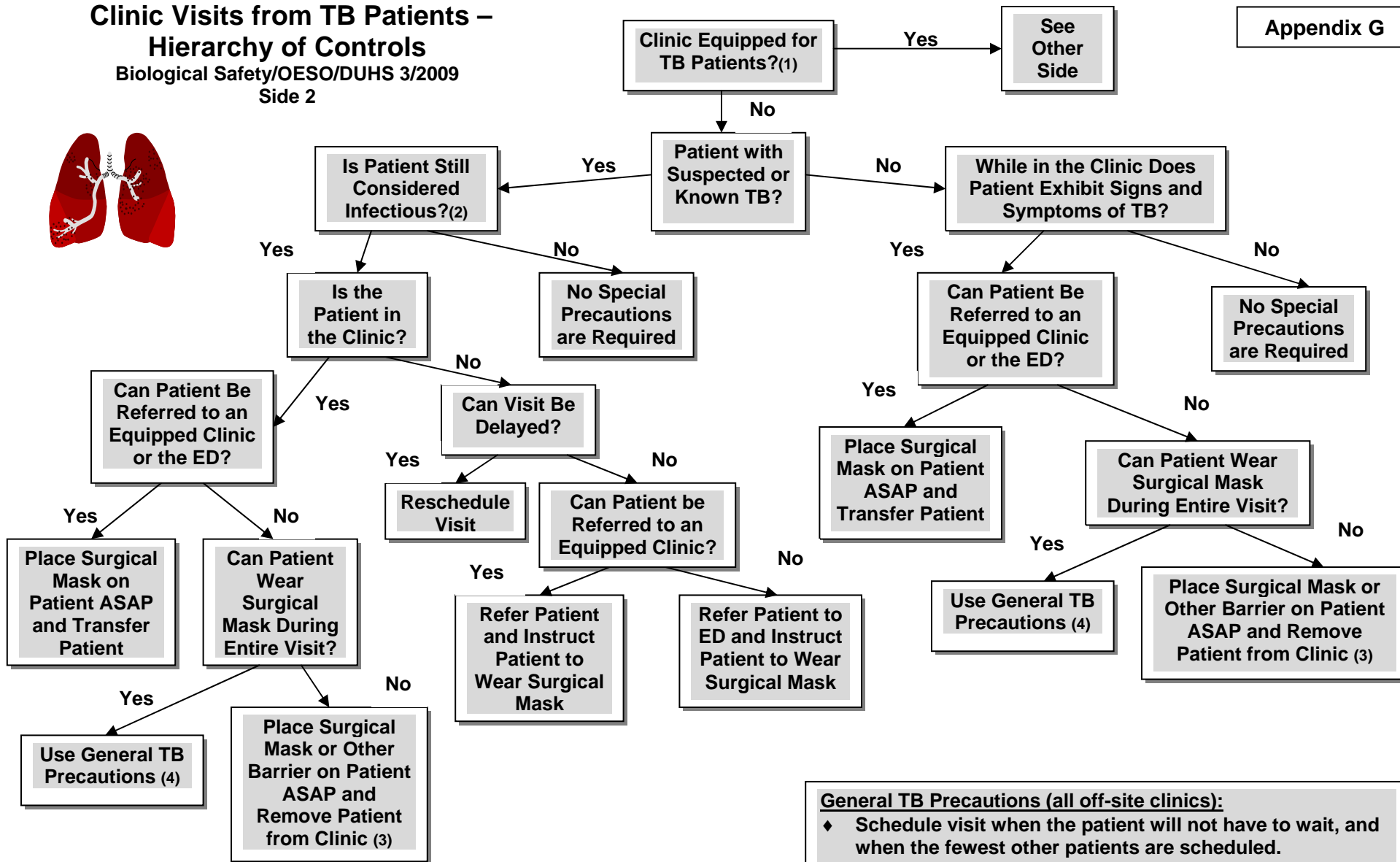
- ◆ Schedule visit when the patient will not have to wait, and when the fewest other patients are scheduled.
- ◆ Instruct the patient to wear a surgical mask when entering the building and keep it on during the entire visit. Respiratory protection is not needed for the employee.
- ◆ Place the patient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

Clinic Visits from TB Patients – Hierarchy of Controls

Biological Safety/OESO/DUHS 3/2009
Side 2



Appendix G



- (1) Fit-Tested Employees or PAPRs and airborne isolation rooms or portable HEPA units available. (All clinics in Duke Clinic)
- (2) Noninfectious is 3 negative sputum smears collected at least 8 hours apart (one specimen a morning specimen), patient is clinically improving, and drug therapy for 2 weeks.
- (3) In an emergency with an unmasked patient a N95 respirator is acceptable temporary protection whether the employee is fit-tested or not.
- (4) Sputum is collected using “Full TB Precautions” at an Equipped Clinic.

General TB Precautions (all off-site clinics):

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

Appendix H: 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"