DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Indian Health Service
Rockville, Maryland 20857 Refer to: OHP

INDIAN HEALTH SERVICE CIRCULAR NO. 95-9

TUBERCULOSIS INFECTION CONTROL POLICY

Sec.

1. PURPOSE To establish responsibilities and procedures for reducing the risk of *Mycobacterium* **(M.)** tuberculosis (TB) transmission in Indian Health Service (IHS) operated health care facilities, and to health care workers (HCW), patients, volunteers, and other persons in these settings.

2. SCOPE. This policy applies to all Indian Health Service. (IHS) employees, including Federal employees assigned to tribally operated programs under Public Law (P.L.) 93-638 the Indian Self-Determination and Education Assistant Act: as amended, and programs funded under Title V of Public Law (P.L.) 94-437, the American Indian Health Care Improvement Act, as amended. Tribally-operated health care facilities are encouraged to adopt this or a similar policy.

3. **OBJECTIVES.**

   A. To prevent the transmission of TB from infected patients or visitors to Health care workers (HCW).

   B. To protect IHS patients and *visitors* to IHS health care facilities from being infected with TB.

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c. To comply with Occupational Safety Health Administration (OSHA) regulations Title 29 Part 1960.16 of the Code of Federal Regulations (CFR) and Executive Order 12196, Section l-201.

4. RESPONSIBILITIES.

A. **Headquarters Technical Consultant on TB Control** The Associate Director, Office of Health Programs (&HP) *or* his/her designee, shall be the IHS technical consultant for the control of exposure to TB.

B. **Area Technical Consultant on TB control** The Area Chief Medical Officer (CMO), or his/her designee, shall be the technical consultant for service units, Title V programs, and P.L. 93-638 contractors. The CM0 shall act as consultant for the implementation of exposure control plans and other aspects of this policy.

C. Service Unit Directors and P.J,. 93-638 Program Directors. The Directors of IHS-operated service units and P.L. 93-638 contracted/compacted programs shall assume.. responsibility for the implementation of the requirements of 29 CFR 1960.16 and Executive Order 12196, Section l-201 at the local level. Implicit in these responsibilities is preventing occupational exposure to TB.

5. POLICY . Managers of each health care facility shall designate an individual or group of persons as the TB control officer *or* the TB control committee. This individual or group is responsible for implementation of the applicable TB exposure control measures contained-in this document. A high level of suspicion on the part of health care providers is a prerequisite for an effective tuberculosis control program. It is the undiagnosed patient who poses the greatest risk. Diagnosis brings about treatment, which usually reduces infectiousness rapidly. An effective TB exposure control program requires early detection, isolation, and treatment of persons with active TB.

A. The TB exposure control program shall be accomplished by the application of a hierarchy of control measures, including:

(1) Use of administrative measures to reduce the risk of exposure to persons with infectious TB;

(2) Use of effective engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei; and

(3) Use of personal respiratory protection equipment in areas where there is still a risk of exposure-to TB such as isolation rooms.

B. Specific TB control measures required include:

(1) A facility-wide or program specific TB risk assessment shall be conducted to identify factors likely to increase exposure, to identify employees at risk of exposure, and to identify control measures necessary to reduce TB exposure.

(2) Each facility or program shall use the information from the risk assessment to develop a TB exposure control plan tailored to that facility. See Appendix C for an example of a model TB exposure control plan.,

(3) Each inpatient facility shall have at least one isolation room that meets the Centers for Disease Control and Prevention (CDC) recommendations for Acid Fast Bacilli isolation. Additional isolation rooms shall be provided based on the results of the risk assessment.

(4) Ambulatory care settings in which patients with TB frequently receive health care services shall have at least one negative pressure room where these patients can be seen. The need for the negative pressure room shall be based on the risk assessment.

(5) Each facility that conducts high risk procedures (sputum induction, administration of aerosolized medication,, etc.) shall have local exhaust ventilation devices (e.g., booths or special enclosures) or *rooms* under negative pressure with at least 12 air changes per hour, where these procedures will be performed.

(6) Each facility shall ensure that all engineering controls utilized to prevent the transmission of TB are properly installed and maintained.

(7) Each facility or program shall develop, implement, and maintain a respiratory protection program to protect employees against TB. The respiratory

protection program must comply with the requirements set forth in the OSHA Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis, and 29 CFR 1910.134.

(8) All HCWs shall receive education about TB that is appropriate to their job category. Training shall be conducted before initial assignment and subsequently on a periodic basis. Contract and agency HCWs shall receive appropriate training by the company/sponsoring agency before assignment at an IHS facility.

(9) All facilities shall have an employee TB skin testing program in place, as described in Appendix A, Tuberculosis Skin Testing Program. The program will apply to all permanent and temporary, full-time and part-time employees, tribal personnel, volunteers and trainees assigned to IHS facilities who are considered by the facility's employee health physician to be at risk for contracting TB by virtue of exposure in the course of their assigned duties.

Screening and prophylactic treatment will be offered in accordance with guidelines published by the IHS, CDC, and the American Thoracic Society. Contract and agency HCWs shall be tested and cleared by the company before assignment at an IHS facility.

(10) Individuals assigned to implement the health care facility TB control program and officials of health departments (tribal, State, local) shall coordinate their efforts to perform appropriate contact investigations on patients and HCWs with active TB. A discharge plan coordinated with the patient or HCW, the health department, and the inpatient facility shall be implemented.

6. REFERENCES.

The IHS Standards of Care for Tuberculosis: INH preventive therapy." me IHS Primary Care Provider. 1989; 14:54-58.

"Treatment of Tuberculosis and Tuberculous Infection in Adults and Children.': Am J Respir Crit Care Med 149:1359-1374, 1994.

'Screening for Tuberculosis and Tuberculous Infection in High-Risk Populations and The Use of Preventive Therapy for Tuberculous Infection in the U.S." m 39: Supplement No. RR-8, May 18, 1990.

Diagnostic Standards and Classification of Tuberculosis. Amer Rev Respir Dis 142:725-735, 1990.

"Prevention and Control of Tuberculosis in Facilities Providing Long Term Care to the Elderly." MMWR 39: Supplement No. RR-l0, July 13, 1990.

Enforcement POlicy and Procedures for Occupational Exposure to Tuberculosis." U.S. Department of Labor (OSHA) Memorandum, October 8, 1993.

Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, 1994." Centers for Disease Control and Prevention: MWWR 43: No. RR-13, October 28, 1994.

"Control of Tuberculosis *in* the United States". Amer Rev Respir DIS 146:1623-1633, 1992.

Appendix B - Definitions of terms related to the control of Tuberculosis.

7. SUPERSEDURE. This circular supersedes IHS Circular 92-14, 'Tuberculosis Testing Program, IHS Personnel - Policy", and the Interim Policy and Procedures for Occupational Exposure to Tuberculosis established by memorandum from the Acting Director, IHS, dated March 11, 1994.

8. EFFECTIVE DATE: This circular is effective upon the date of signature by the Director, IHS.

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TUBERCULOSIS INFECTION CONTROL POLICY

TUBERCULOSIS SKIN TESTING PROGRAM

This section (Appendix A). outlines the Indian Health Service (IHS) policy and procedures regarding tuberculin testing and prophylactic treatment for employees working within IHS facilities or programs.

1. **Health Care Workers (HCWs) Purified Protein Derivative (PPD) Tuberculin Skin Test Screening.**

   A. Employee Surveillance

   All IHS facilities shall have an employee TB screening program in place.

   The program will apply to all permanent and temporary, full-time and part-time employees, tribal personnel, volunteers and trainees assigned to IHS facilities who are considered by the facility's employee health physician to be at risk for contracting TB by virtue of exposure in the course of their assigned duties. Consideration should also be given to personnel in tribally operated nursing and other group homes that serve the same patient population.

   Screening and prophylactic treatment offered will be in accordance with guidelines published by the IHS, Centers for Disease Control and Prevention (CDC), and the American Thoracic Society (ATS).

   B. Employee Screening

   Covered employees shall have a tuberculin test at the time of employment. If an employee is known to have had a positive tuberculin test prior to entry on duty, no tuberculin testing will be carried out; instead, the employee will be referred to the employee health physician to establish an individualized program to assure the absence of active TB in the employee. This may include one or more chest x-ray examinations as well as documentation of prior testing and treatment.

   The employee health physician shall review all available records and x-rays if an employee is known to

have had a positive tuberculin test prior to entry on duty , and shall encourage the employee to accept preventive therapy, unless contraindicated or the employee refuses. When preventive therapy is instituted, it is the responsibilitys of the locally designated TB control physician to oversee the administration of such therapy.

C. Tuberculin Skin Test.

The Mantoux technique tuberculin skin test is the method of choice for TB screening, (i.e. tine testing is not acceptable). The One-tenth milliliter of PPD (Stu) is injected just beneath the surface of the skin of left forearm. A discrete, pale elevation of the. skin (i.e. a wheel) that is 6-10 mm in diameter should be produced. (More complete summary may be found in the MMWH, Table: S2-1, P.62.) This technique is preferred for screening person6 for TB infection, because it is the most accurate test available. A 2-step procedure should be used initially to minimize the likelihood of misinterpreting a boosted reaction for a recent infection. In the a-step procedure, an initial tuberculin Skin test (Mantoux 5 Stu PPD) is given. If this test result is O-9 millimeter (mm) of induration, a second test is given at least 1 week and not more than 3 week6 after the first. The result of the second test should be ***used*** as the baseline test in determining treatment and follow up of converters/reactors. Skin test result6 should be recorded in mm of induration and not as "positive" or "negative."

D. Interpretation of Results.

Interpretation varies according to the risk factor6 associated with the group/individual being tested. In general, the recommendations for interpreting Skin test results for HCW are equivalent to other member6 of high or low risk groups. (See Table 52-1, MMWR, Vol. 43/No. RR-13, p62.)

(1) The prevalence of TB in the facility should be considered when choosing the appropriate cut-point for defining a positive PPD reaction. In facilities where there is essentially no risk for exposure to Mycobacterium tuberculosis (i.e., minimal- or very low-risk facilities), an induration of >= 15 mm may be a suitable cut-point for HCWs who have no other risk factors. In facilities where TB patients receive

care, the cut-point for health care workers with no other risk factors may be 210 mm.

(2) A recent conversion in a HCW should be defined generally as a >=10 mm increase in size of induration within a 2-year period. For HCW who work in facilities where exposure to TB is very unlikely, a increase of >=15 mm induration may be more appropriate.

(3) Any employee initially manifesting a positive tuberculin reaction shall have a chest x-ray done.

(4) Recent converters, as indicated by a PPD increase of l0-mm induration within 2 years for those up to 35 year6 of age, and a PPD increase of >= 15-mm induration for those 35 years old and older.

Any employee initially manifesting a positive tuberculin reaction shall have a chest x-ray done.

E. Periodic Repeat Test

The required frequency of repeat risk assessment and PPD skin testing is based on the level of risk minimal, "very low," "low," "intermediate," or "high") assigned by the most recent risk assessment. The frequencies are as follows:

(1) Annually for "minimal" "very low," or "low risk" areas.

(2) At 6 month interval6 for "intermediate risk" areas, and

(3) At 3 month intervals for "high risk" areas.

(See Appendix B for definitions of "minimal," "very low," "low," "intermediate," and "high" risk).

F. For HCWs With Significant Reactions

Smear and culture examination of at least three sputum specimens collected on different days is the main diagnostic procedure for pulmonary TB. (P.64, MMWR)

During TB screening, it is important to obtain an initial chest radiograph on those person6 with significant skin-test reactions, those who convert their skin test, or those who have pulmonary symptoms that may be due to TB.

There is no need to obtain routine chest films of asymptomatic, tuberculin-negative personnel. After initial chest films of persons with significant reactions, repeated chest x-ray examinations have not been found to be of value. Significant reactors, whether or not they complete preventive treatment, do not need repeat chest films unless they have pulmonary symptoms that may be due to TB.

For positive skin test reactions without evidence of disease, the most current recommendations for chemoprophylaxis as published by the IHS, ATS, and CDC should be considered. Any x-ray change6 and a variety of underlying diseases must be evaluated on a case by case prior to a final decision on preventive therapy.

G. HCWs Exposed to Tuberculosis.

When unprotected employees are exposed to a patient with active TB, the designated TB control person(s) Shall immediately make a list of those employees (and patients) who are contacts (i.e. those who have shared air with the patient). Any contacts who have not completed baseline screening should be tested as soon as possible. Skin testing of all exposed tuberculin-negative employees should be completed within **l0-12** weeks.

(1) Any employee6 whose tuberculin reaction converts from negative to positive shall have a Chest x-ray.

(2) Such an employee shall be offered appropriate chemoprophylactic therapy. At the discretion of the employee health physician, chest x-ray may be repeated after the completion of the course of chemoprophylaxis.

(3) Employees who convert their tuberculin test and who decline chemoprophylaxis should be considered for a chest x-ray examination every 3 months for 1 year and every 6 months for the next 2 years, since they are at high risk for developing active disease during that time.

(4) If the employee health physician determines that any employee has developed TB with active disease, such employee shall receive appropriate chemotherapy. The employee shall be deemed non-infectious before returning to duty. The employee health physician Shall also notify the appropriate public health

authorities of the case and arrange for such additional contact examination as may be necessary.

(5) Incidents resulting in the conversion of an employee's skin test to positive or causing active disease should be reported in accordance with the facility's incident reporting program.

H. **Separation**.

A tuberculin test prior to separation Shall be done for all covered employees, unless the employee is known to be tuberculin positive.

I. Records.

All employees records pertaining to TB, including all x-rays, Shall be retained with the employee's occupational health record.

J. Accountability

The designated employee health specialist (See Indian Health Manual Part 1, Chapter 9) shall review the employee tuberculin testing program on a yearly basis, as a part of the overall employee health program. A copy of the skin testing policy shall be made available to each covered employee. Additionally, TB infection control training shall be provided at the time of assignment to tasks where occupational exposure may occur, and the training shall be repeated periodically.

2. **Return to Work policy for HCW's with active TB**.

A. Individual6 with evidence of active pulmonary disease are not medically cleared to enter or return to the work site until they have evidence of a definite clinical and bacteriologic response to therapy (i.e., reduction in cough, resolution of fever, and consecutive negative smears for acid fast bacilli. In general, this response occurs after the individual has been on adequate chemotherapy for at least two to three weeks.

B. Individuals without evidence of active pulmonary disease are strongly encouraged to follow the medical advice provided (e.g., prophylactic treatment if a new converter or less than (<) 35 years of age) and are contacted again in a month by the TB control officer to determine their elected course of action. These individual6 are medically cleared to enter or return to the work site

directly. Compliance with any prescribed prophylactic treatment remains the responsibility of the individual and his/her personal pnysician or the community health clinic. HCWs with without evidence of active pulmonary disease who cannot take or who do not accept or complete a full course of preventive therapy should not be excluded from the workplace. These HCWs shall be counseled about the risk for developing active TB and instructed regularly to seek prompt evaluation if signs or symptoms develop that could be caused by TB.

TUBERCULOSIS INFECTION CONTROL POLICY

DEFINITIONS

1. Acid-Fast Bacilli (AFB) - Bacteria that retain certain dyes even when washed with an acid solution. Most acid-fast organisms are mycobacteria *(M. tuberculosis).* When seen on a stained smear of sputum or other clinical specimen, a diagnosis of TB should be considered; however, the diagnosis is not confirmed until a culture is grown and identified as M. *tuberculosis.*

2. Acquired Drug Resistance - Resistance to one or more anti-tuberculosis drugs which develops while a patient is on therapy, usually the result of non-adherence on the part of the patient or inadequate therapy prescribed by a health care provider.

3. Adherence - Refers to the completion by patients of all aspects of the treatment regimen as prescribed by the medical provider. Also refers to health care workers (HCWs) and employers following all guidelines pertaining to infection control.

4. Aerosol Aerosolization - In TB, it refers to the infectious droplet nuclei that are expelled from a person which can be transmitted to other people.

5. Air Changes - Air flow quantity to a space measured in terms of the room volume. i.e., volume of air delivered divided by room volume. Usually expressed as number of air changes per hour.

6. *Alveoli* - The small air sacs in the lungs which lie at the end of the bronchial tree. The site where carbon dioxide is replaced by oxygen in the lungs, and the site where TB infection usually begins.

7. Anergy - The inability of a person to react to skin-test antigens because of defects in the immune system, even if the person is infected with the organisms tested.

8. Anteroom - A small room located between an isolation room and a corridor that acts as an airlock, preventing escape of room contaminants into the corridor.

9. Asymptomatic - Showing or causing no symptoms.

10. Bactericidal - Capable of killing bacteria. Isoniazid and rifampin are the two most potent bactericidal antituberculosis drugs (See Bacteriostatic).

11. Bacteriostatic - Capable of preventing bacterial growth but not necessarily capable of killing bacteria. Drugs such as ethambutol and para-aminosalicylic acid are primarily bacteriostatic (see Bactericidal)

12. BCG (Bacillus of Calmette and Guerin) - A TB vaccine widely used in some parts of the world.

13. Booster Phenomenon - Seen when an individual with infection does not react to tuberculin because his/her body's cell responses to tuberculin have gradually waned over the years. An initial tuberculin test may stimulate (boost) the immune system so that the next test will be positive. This phenomenon is important in infection control in order to distinguish between recent converters and people who have been infected for a long time, and determine if in fact transmission is taking place. Although the booster phenomenon may occur at any age, it is most frequent among persons over 55.

14. Bronchoscopy - A procedure for examining the respiratory tract by inserting an instrument (bronchoscope) through the mouth or nose into the trachea. Diagnostic specimens can be obtained during bronchoscopy.

15. Cavity - A hole in the lung resulting from destruction of pulmonary tissue. May be caused by TB, but also by other pulmonary infections and conditions. TB patients with cavities in their lungs are said to have "cavitary disease" and are often more infectious than patients without cavities.

16. Chemotherapy - Treatment of an infection or disease by means of oral or injectable drugs.

17. Chest Radiograph - In patients showing signs or symptoms of TB, a radiograph of the chest is taken to view the respiratory system. Abnormalities, such as lesions or cavities in the lungs and enlarged lymph nodes, may indicate the presence of TB.

18. Contact - An individual who has shared the same air as a person with infectious TB for a sufficient amount of time so that there is a probability that transmission of TB has occurred.

19. Conversion, PPD - See PPD TEST CONVERSION

20. Culture - The process of growing bacteria in the laboratory so that organisms can be identified.

21. Dilution Ventilation - An engineering control technique to dilute and remove air-borne contaminants by the flow of air into and out of the area. Air that contains droplet nuclei is removed and replaced by air that is free of contaminants. If the flow is sufficient, droplet nuclei become dispersed, and their concentration in the air is diminished.

22. Droplet Nuclei - Microscopic particles (1 to 5 microns in diameter) produced when a person coughs, sneezes, shouts, or sings. The droplets can carry tubercle bacilli and remain in the air by normal air currents in the room;

23. Drug Sensitivity - See Drug Susceptibility Pattern

24. Drug Susceptibility Pattern - The antituberculosis drugs to which a tubercle bacillus is, susceptible and those to which it is resistant based on susceptibility tests.

25. Drug Susceptibility Tests - Laboratory tests which determine if the tubercle bacilli cultured from a patient is susceptible or resistant to various antituberculosis drugs.

26. Exposure - The condition of being subjected to something, such as infectious agents, which may have a harmful effect. A person exposed to TB does not necessarily become infected (see Transmission).

27. Fomites - Linens, books, dishes, or other objects used or touched by a patient. They are not involved in the transmission of TB.

28. HEPA (High-Efficiency Particulate Air) - Filter - Specialized filter that is capable of removing 99.97% of. particles 0.3 microns in diameter. It may be of assistance in control of TB transmission. Requires expertise in installation and maintenance.

29. Human Immunodeficiency Virus (HIV) or HIV Infection - Infection with the virus that causes the acquired immunodeficiency syndrome (AIDS). It is the most potent risk factor for progression from TB infection to active TB.

30. HCW - Health Care Worker

31. High Risk - High risk areas or groups are those in which (1) the PPD test conversion rate is significantly greater than areas without occupational exposure to TB patients ***or*** than previous rates in the same area or group, or (2) there is a cluster of PPD test conversions, or (3) there is other evidence of 'patient-to-patient or patient-to-HCW transmission of TB.

32. Immunosuppressed - Persons with severe cellular immunosuppression (i.e HIV infected or organ transplant patients on immunosuppressive therapy). These patients are at greatly increased risk for developing TB once infected. There are no data available on whether they are also at higher risk of becoming infected with M. tuberculosis, if exposed.

33. Induced Sputum - Sputum obtained from a patient unable to cough up a spontaneous specimen. The patient inhales a mist of saline (salt water), which stimulates a cough from deep within the lungs. ,

34. Induration - The area of swelling that surrounds the site of injection of tuberculin. The diameter of the indurated area is measured (in millimeters) 48-72 hours after the injection and is recorded as the result of the PPD test.

35. Infection - The condition in which organisms capable of causing disease (e.g., ***M. Tuberculosis)*** multiply within the body and cause a response from the host's immune defenses. Infection may or may not lead to clinical disease.

36. Infectious Capable of causing infection. In TB a person is infectious only if he/she has clinically active TB TB patients whose sputum is AFB smear positive are often infectious.

37. Intermediate Risk - Intermediate risk areas or groups are those in which; (1) the PPD test conversion rate is not greater than in areas or groups without occupational exposure to TB patients or than previous rates in the same area or group; (2) there are no clusters of PPD test conversions; (3) there is no evidence of patient-to-patient transmission; and (4) there are 6 or more TB patients hospitalized per year.

38. Intradermal - Within the layers of the skin.

39. Local Exhaust Ventilation - Used as a source control technique to capture and remove air-borne contaminants by

enclusing the contaminant source or by means of a hood placed very near the contaminant source.

40. Low Risk - Low risk areas or groups are those in which (1) the PPD test conversion rate is not greater than in areas or -groups without occupational exposure to TB patients ***or*** than previous rates in the same area or group, (2) there are no clusters of PPD test conversions, (3) there is no evidence of patient-to-patient transmission, and (4) (in the case of an area) there are < 6 TB patients hospitalized per year.

41. - Mantoux Test - A tuberculin test given by injecting a measured amount of liquid tuberculin into the dermis (second layer of the skin) with a needle and syringe. It is the most reliable and best standardized technique for tuberculin testing (see Tuberculin Skin Test and Purified Protein Derivative Test).

42. MDR (Multidrug Resistant) Tuberculosis - Tuberculosis bacteria resistant to multiple drugs which normally kill them (see Resistance)

43. Minimal Risk - Facilities may be described as having a minimal risk of TB exposure if no TB cases are present in the community and no TB patients were seen as inpatients or outpatients.

44. Mycobacterium Tuberculosis Complex - The complex of mycobacterial species that causes TB; it includes M. tuberculosis, M. bovis, and M. africanum.

45. Negative Pressure - A term used to describe the relative air pressure difference between two areas of the health-care facility. Air will flow from the higher pressure area into the lower pressure area.

46. Non Contagious Tuberculosis - See Tuberculosis Infection

47. Pathogenesis - The natural development of a disease in the body without intervention (i.e., without treatment).

48. PPD - See Purified Protein Derivative

49. Portable Filtration Units - Portable devices that provide contaminant dilution by recirculating air within a room through a HEPA filter.

50. Positive PPD Reaction - A reaction to the purified protein derivative (PPD) test that suggests the individual tested is infected with tubercle bacilli. Determination of the

reaction is largely dependent on interpretation by the person evaluating the test given the patient's or HCW's medical history and risk factors.

51. Preventive Therapy - Chemotherapy of TB infection, primarily used to prevent progression of infection to clinically active disease.

52. Primary Drug Resistance (PDR) - Resistance of bacteria to drugs which exists before the 'beginning of treatment (see Acquired Drug Resistance).

53. Purified Protein Derivative (PPD) - A type of purified tuberculin preparation derived from old tuberculin (OT) and developed in the 1930's. The standard Mantoux test uses 5 TU (tuberculin units) of PPD.

54. Purified Protein Derivative (PPD) Reactor - A person with a positive skin test, who does not have a documented negative skin test within the last two years.

55. Purified Protein Derivative (PPD) Test - A method to determine whether a person is infected with Mycobacterium tuberculosis. A small dose of the antigen from M. tuberculosis is injected just beneath the surface of the skin and the area is examined 48-72 hours after the injection. A positive reaction is measured according to the size of the induration. The classifications for positive reactions depend on the patient's medical history and various risk factors (see Mantoux Test).

56. Purified Protein Derivative (PPD) Test Conversion - Growth in induration within a two-year period after an initial negative reaction with a difference of 10 or more millimeters of, induration. Such "conversion" may represent new infection which is associated with high risk of developing disease,, or may occur as a result of the Booster Phenomenon.

57. Reaction - See Purified Protein Derivative (PPD) Reactor

58. Recirculation - Ventilation where all or most of the air exhausted from an area is returned to the area.

59. Regimen - Any particular treatment plan for TB specifying which drugs are used, in what doses, according to what schedule, and for how long.

60. Registry - A record-keeping method to collect clinical, laboratory, and radiographic data on TB or any other

pathological field so the data can be organized and properly processed to be made available for epidemiologic study;

61. Resistance - The ability of some strains of bacteria (including M. tuberculosis) to grow and multiply even in the presence of certain drugs which normally kill them. (such strains are referred to as "drug resistant strains.“)

62. Respirator Fit Check - A fit check is a maneuver that a HCW performs before each use of the respiratory protective device to check the fit. The fit check should be performed according to the manufacturer's facepiece fitting 'instructions.

63. Respirator Fit Test - A fit test is used to determine whether a respiratory protective device adequately fits a particular HCW. Determination of facepiece fit can involve qualitative or quantitative tests. A qualitative test relies on the wearer's subjective response. A quantitative test uses detectors to measure inward leakage.

64. Qualitative Fit Test - A subjective test utilized to determine if a respirator fits the wearer appropriately. The wearer is exposed to a test agent (irritant smoke or other suitable agent) easily detectable by irritation or taste. If the wearer is unable to detect penetration of the test agent the respirator is probably tight enough.

65. Quantitative Fit Test - A quantitative fit test uses a probe inserted through the device to determine the concentration of a substance inside the respirator compared to the concentration of the substance outside the respirator.

66. Secondary Drugs - Antituberculosis drugs used in difficult cases (such as for retreatment or when there is resistance to primary drugs). Examples are cycloserine, ethionamide, capreomycin.

67. Single Pass Ventilation - Ventilation in which 100% of the air supplied to an area is exhausted to the outside.

68. Smear (AFB Smear) - A laboratory technique for visualizing mycobacteria. The specimen is smeared onto a slide and stained, and then placed under the microscope for examination. Smear results should be available within 24 hours. A large number of mycobacteria usually indicates infectiousness; however, a "positive" result is not definitive for TB.

69, Source Case - An infectious individual who 'has transmitted tubercle bacilli to anotherperson or persons.

70. Source Control - Control of a contaminant at the source of generation rather than permitting it to enter the general work space.

71. Specimen - Any body fluid, secretion, or tissue sent to the laboratory where smears and cultures for tubercle bacilli will be performed. The specimen may consist of sputum, urine, spinal fluid, material obtained at biopsy, etc.

72. sputum - Material coughed up from deep within the lungs. If a patient has a pulmonary infection, an examination of the sputum by smear and culture can indicate what organism is responsible for the infection. It should not be confused with saliva or with nasal secretions.

73. Sputum Smear Positive - The AFB are visible after staining when viewed under a microscope. The TB culture positive individuals with sputum smear positive for AFB are considered more infectious than those with smear negative sputum.

74. Suspect Case - A person suspected of having active contagious tuberculosis disease.

75. Symptomatic - Having symptoms which may be clues to the presence of TB or another disease (see Asymptomatic).

76. Transmission - The spread of an infectious agent like Mycobacterium tuberculosis from one individual to another. The duration and intensity of exposure to TB is directly related to the likelihood that transmission will occur and a person will become infected (see Exposure).

77. Treatment Failures - Refers to individuals who fail to improve even after a course of chemotherapy is begun, and to individuals whose disease worsens after having initially improved.

78. Tubercle Bacilli - The term often used to refer to the organism Mycobacterium tuberculosis.

79. Tuberculin Skin Test - A method to determine whether a person is infected with Mycobacterium tuberculosis. A small dose of the antigen from M. tuberculosis is injected just beneath the surface of the skin and the area in examined 480 72 hours after the injection. A positive reaction is measured according to the size of the swelling. The

classifications for positive reactions depend on the patient's medical history and various risk factors (see Mantoux Test, PPD Test).

80. Tuberculosis (TB) - A clinically apparent, active disease process caused by Mycobacterium ***tuberculosis,*** complex (usually M. ***tuberculosis, or,*** rarely, ***M. bovis*** or M. africanum).

81. Tuberculosis Case - A particular instance of clinically active TB_I It is sometimes used incorrectly to designate the individual with the disease.

82. Tuberculosis Infection - A condition in which living tubercle bacilli are present in the body, without producing clinically active disease. Although the infected individual has a positive tuberculin reaction, he/she has no symptoms related to the infection and is not infectious. However, the infected individual remains at lifelong risk of developing disease unless preventive therapy is given.

83. Tuberculosis (TB) Isolation Precautions - Infection control procedures that should be applied when persons with known or suspected infectious TB are hospitalized or residing in other inpatient facilities. These precautions include the use of a private room with negative pressure in relation to surrounding air and removal of air from the room directly to the outside. Not the same as "respiratory isolation[11] which calls for a private room, but does not require negative pressure and exhaust of room air to the outside.

84. Two-Step Testing - A procedure used among people who ***receive*** tuberculin skin tests periodically (such as health care workers) to reduce the likelihood of mistaking a boosted reaction for a recent infection. If the initial tuberculin test is classified as negative, a second test is repeated one week later. If the reaction to the second test is positive, it probably represents a boosted reaction. If the second test result remains negative, the person is classified as being uninfected.

85. Ultraviolet (W) Lamps - Lamps that destroy germs by emitting radiation predominantly at a wavelength of 254 nanometers (intermediate between visible light and X-rays). They can be used in ceiling or wall fixtures or within air ducts of ventilation systems. The effectiveness for infection control in health care facilities is not yet proven.

86. Very Low Risk - A facility may be described as having a very low risk if no TB patients were admitted as inpatients nor ,, examined as outpatients in the preceding year, and the exposure control plan states that any patients with confirmed or suspected TB will be referred to another facility.

87. Virulence - Refers to the ability of a microorganism, such as M. tuberculosis, to produce serious disease. The M. tuberculosis is a virulent organism. Some nontuberculous mycobacteria are virulent (e.g., M. kansasii), while others (e.g., M. gordnae) are not. (Pathogenicity is a related, though not identical, concept).

[Please note: This model exposure control plan is intended to be adjusted to meet the needs of the local program. Sections should be added, deleted or modified as required.]

INDIAN HEALTH SERVICE

_____
Area, Service Unit, or Facility Name]

TUBERCULOSIS EXPOSURE CONTROL PLAN

This Exposure Control Plan (ECP) applies to all employees, volunteers, and students in the- _____ [name of area, service unit, or facility] including Federal employees assigned to Public Law 93-638 facilities.

1. PURPOSE. The purpose of this ECP is to eliminate or reduce as much as possible, employee, patient, and visitor exposure to Mycobacterium (M.) ***tuberculosis*** (TB).

2. BACKGROUND. Since 1985, the rate of new cases of tuberculosis in the general U.S. population increased 18 percent, reversing a 30-year downward trend. As the incidence of TB increased, occupational exposure among HCWs also increased. Nationally, during this time period, several hundred employees were infected from work place exposure to TB requiring medical treatment. Sixteen HCWs developed active multi-drug resistant tuberculosis (MDR-TB). There were at least five health, care workers (HCW) deaths due to MDR-TB. Drug resistant strains of TB are now a serious concern with cases being reported in forty states.

   Due to the resurgence of TB and the dangers associated with drug resistant strains, the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA) published guidelines and enforcement actions related to TB. OSHA issued its "Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis" in October, 1993. CDC "Guidelines for Preventing the Transmission of Tuberculosis in Health care Facilities, 1994" were published in the October 28, 1994, Federal Register. The OSHA enforcement policy was based on the earlier 1990 CDC guidelines; however, it is likely that OSHA will begin citing the more recent CDC guideline. OSHA utilizes the "General Duty Clause" (section 5-a-l) of the Occupational Safety and Health Act to enforce these policies and procedures. While many health care facilities have components of a TB

prevention program, the CDC and OSHA documents are now forcing a consistent, comprehensive approach. This TB ECP is intended to meet that need. Effective January 8, 1994, the OSHA began enforcing the requirement that HCWs wear High Efficiency Particulate Air (HEPA) respirators when potentially exposed to TB. The circumstances which OSHA considers as potential exposures are relatively well defined in their enforcement policy and in this document.

3. EPIDEMIOLOGY, TRANSMISSION, AND PATHOGENICITY OF TB TB is not evenly distributed throughout all segments of the U.S. population. Some subgroups or individuals have a higher risk of TB either because they are more likely than the general population to have been exposed to and infected by TB or because they are more likely to progress to active TB once infected. In some cases, both of these factors may be present.

Suspect populations include: Native Americans, immigrants from countries with high incidence of TB, homeless persons, past/current prison inmates, alcoholics, intravenous drug users, the elderly, and contacts of persons with active TB. Persons with higher incidence of progression from latent to active TB include persons with such medical conditions as: Human Immunodeficiency Virus (HIV) infection, silicosis, post gastrectomy, jejuno-ileal bypass surgery, being 10 percent less than ideal weight, chronic renal failure, diabetes mellitus, immunosuppression due to high doses of immunosuppressive therapy, and some malignancies. Also included are those: infected with TB within the last two years, children less than 3 years, and persons with fibrotic lesions on chest radiographs. Symptoms of TB include: a cough lasting 2 weeks or greater, bloody sputum, night sweats, weight loss, anorexia, and fever,

The TB organism is carried in airborne particles known as droplet nuclei, that can be generated when persons with pulmonary or laryngeal TB sneeze, cough, speak, or sing. The particles are estimated to be approximately l-5 microns in size, and normal air currents keep them airborne and can spread them throughout a room or building. Infection occurs when a susceptible person inhales droplet nuclei containing TB, and bacilli are able to traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli of the lungs. Once in the alveoli, the organisms are taken up by a alveolar macrophage and spread throughout the body. Usually within 2 to 10 weeks after initial infection with TB, the immune response limits further multiplication and spread of the tubercle bacilli; however, some of the bacilli remain dormant and viable for many years. This is

known as latent TB infection. Persons with latent TB infection usually have a positive purified protein derivative, (PPD) skin test, no symptoms of active TB, and are not infectious. In general, persons with latent TB infection have approximately a 10% risk during their lifetime for the development of active TB. The risk is greatest in the first 2 years after infection, but some risk persists for decades.

Persons with immunocompromising conditions have a greater risk for the progression of latent TB infection to active disease. The HIV is the strongest known risk factor yet identified for the progression from latent TB infection to active TB disease. Persons with latent TB infection who become infected with HIV have approximately an 8 to 10 percent risk per year for the development of active TB. Persons who are infected with HIV and become newly infected with TB have an even greater risk for the development of active TB.

The probability that a susceptible person will become infected with TB depends primarily upon the concentration of infectious droplet nuclei in the air and the duration of exposure. Characteristics of the TB patient that enhance transmission include: (1) Disease in the lungs, airways, or larynx, (2) presence of cough or other forceful expiratory measures, (3) presence of acid-fast bacilli (AFB) in the sputum, (4) failure of the patient to cover the mouth and nose when coughing or sneezing, (5) presence of cavitation on chest radiograph, (6) short duration of adequate chemotherapy, 'and (7) administration of procedures that can induce coughing or cause aerosolization of TB (e.g., sputum induction, administration of aerosolized medication, etc.). Environmental factors that enhance the likelihood of transmission include: (1) exposure of susceptible persons to an infectious person in relatively small enclosed spaces, (2) inadequate local or general ventilation that results in insufficient dilution and/or removal of infectious droplet nuclei, and (3) recirculation of air containing infectious droplet nuclei.

4. FACTORS IN NOSOCOMIALION OF TB The transmission of TB is a recognized risk in health car;! facilities. The magnitude of the risk varies considerably by type of health care facility, prevalence of TB in the community, patient 'population served, job category, area of the health care facility in which a person works, and the effectiveness of

TB infection control interventions. The-risk may be-higher in areas where patients with TB are provided care before diagnosis and initiation of TB isolation precautions (e.g. clinic waiting areas and emergency rooms) or where diagnostic or treatment procedures that stimulate coughing are performed. Nosocomial transmission of TB has been associated with close contact with infectious patients or HCWs and during procedures such as bronchoscopy, endotracheal intubation and suction, open abscess irrigation and autopsies. Sputum induction and aerosol treatments that induce cough may also increase the potential for TB, transmission. Health care personnel should be particularly alert to the need for preventing TB transmission in health care facilities in which immunocompromised persons, such as persons with HIV infection, receive care and/or work.

Several TB outbreaks in health care facilities have been reported during the past several years. Some of these outbreaks involved transmission of MDR strains of TB to both patients and HCWs. Most of the patients and some of the HCWs were HIV infected persons in whom new infection progressed rapidly to active disease. Mortality associated with those outbreaks was very high (range 43 to 93 percent). Furthermore, the time between diagnosis and death was very short with the median interval ranging from 4 to 16 weeks. Factors contributing to these outbreaks included delayed diagnosis of patients with TB, delayed recognition of drug resistance, delayed initiation of effective therapy resulting in prolonged infectiousness, delayed initiation and inadequate duration of TB isolation, inadequate ventilation in TB isolation rooms, lapses in TB isolation practices, and inadequate precaution for cough inducing procedures. There is evidence from three of the facilities that MDR-TB transmission decreased significantly or ceased in areas where measures similar to those provided in this ECP were implemented.

5. RISK ASSESSMENT. A risk assessment of _____ [list/name of the facility/clinic] shall be completed by the designated TB control [specify either: officer, physician, or committee] at least once every three years, or more frequently if the incidence of TB in the community has changed or there has been a change in procedures or facility design that may increase the risk of TB exposure. The risk assessment may be conducted of the entire facility ***or*** may assess individual areas (or occupational groups) in the institution. Historical information (prevalence of TB in the service area, number of TB patients encountered in each

setting, and HCW PPD skin test conversions) was used to classify tasks/procedures as to level of risk. The TB control measures outlined in section 6 are based on this risk assessment. Based on the assessment, _____ [specify the: facility, area(s), or occupational group(s)] is/are classified as [specify: high, intermediate, low, very low, or minimal] risk.

A. Policies and Procedures

Policies and procedures (P&P) were reviewed to ensure that appropriate administrative TB control measures were being followed. These administrative measures include staff training on early identification, appropriate isolation, rapid access to lab tests/results, mandatory skin testing program, and appropriate treatment of TB patients. These policies and procedures (TB skin testing policy, AFB isolation, and etc. _____[1] [list the P&P related to TB] are located at _____ [list where P&P are kept].

B. High risk Procedures

High risk procedures conducted at the facility or conducted by HCWs at other sites (home care, ambulance, etc.) were identified and include [list high risk procedures, location, and staff involved. Examples are given],:

High Risk Task	Location Of Task	Staff Involved
Sputum Induction	Room # _____	RN, RT
Bronchoscopies	Room # _____	RN, MD,
Isolation rooms	Room #s _____	Nur, MD, Hskp,
Aerosolized drugs	Room #s _____	Nur, Resp Ther,
Sputum Induction	Home Care _____	CHRs & RN
Other [Specify] _	_____	_____
_____	_____	_____
_____	_____	_____

C. Respiratory Protection Program

The respiratory protection program was reviewed to ensure that staff exposed to high risk situations (see above) were appropriately protected. This assessment included identifying situations/tasks that require use of respiratory protection, identifying, employees (by job category) that are required to perform, those tasks, and

review of the respirator assignment program (medical evaluation, fit testing, training, care, and replacement) to ensure that it meets minimal requirements (29 CFR 1910.134).

D. Engineering Controls

Engineering controls used to reduce exposure to TB were identified and evaluated to determine if they provide adequate protection. The engineering controls used in this facility include [list all engineering controls used and their location]:

Engineering Control	Location [Specify building, room number, air handling unit, etc.]
Isolation Rooms	
Sputum Induction Booth(s)	
Biological Safety Cabinet	
HEPA Filters	
other [Specify]	

6. PROCEDURES

There are three approaches to effectively controlling exposure to TB which are used in this ECP. In order of importance, these methodologies are administrative controls (rapid detection, isolation, and treatment), engineering controls (control of air flows, filtering recirculated air, direct discharge of exhaust air), and respiratory protection (HEPA respirator use).

A. **Early Detection of Patients With TB** The HCWs who are the first points of contact (emergency ***rooms*** outpatient clinics, inpatient admissions, home health) in serving patients at risk for TB shall:

(1) Be familiar with the signs and symptoms associated with TB (TB should be considered in any patient with a persistent cough greater than (>) 2 weeks duration, bloody sputum, night sweats, weight loss, anorexia, and/or fever).

(2) Be trained to ask appropriate questions which will help recognize and detect patients with signs and symptoms suggestive of TB.

(3) Ensure patients with signs or symptoms suggestive" of TB are evaluated promptly to minimize the time spent in ambulatory care areas. Such patients shall have TB precautions applied while the diagnostic evaluation is being conducted.

(4) Diagnostic measures should be used on patients suspected of having TB. Immunosuppressed patients with pulmonary signs or symptoms that are initially ascribed to other etiologies should be evaluated for co-existing TB initially, and the evaluation should be repeated if the patient does not respond to appropriate therapy for the presumed etiology. These diagnostic measures typically include:

a. Obtaining an appropriate history (medical, social, etc.), conducting a physical examination, PPD skin testing, chest radiograph, and microscopic examination and culture, of sputum or other specimens.

b. Other diagnostic methods, such as bronchoscopy or biopsy, may be indicated for some patients.

Laboratories shall use the most rapid methods available. Results of AFB smears of sputum should be available from the lab conducting the test within 24 hours of receiving the specimen.

B. Management of OutPatients With Possible TB

The following precautions shall be implemented when a patient suspected or known to have infectious TB is seen in the ambulatory care setting.

(1) The patient will be placed in a separate waiting area apart. from other patients and not in open waiting areas, ideally, in a negative pressure room.

(2) In the outpatient area room # [list room #] is the designated TB treatment room and in the emergency room area room # _____ [list room #1] is the designated TB treatment room.

(3) Staff are required to wear a HEPA respirator when entering the room where the patient is located. The patient will wear a surgical mask, especially if they are transported to a different location in the facility. Family members who must be in the

room should also be asked to wear a surgical mask. If possible, the patient will not leave this designated room(s) for any procedures unless absolutely necessary. Access to the room for both staff and family shall be limited to essential persons only.

(4) Patients are to be given tissues and instructed to cover their mouths and noses when coughing or sneezing.

(5) Patients with known active TB who need to be seen in a clinic shall have appointments scheduled to avoid exposing HIV-infected or otherwise severely immunocompromised persons.

(6) When high risk procedures (sputum induction, administration of aerosolized medication, etc.) are conducted on patients known or suspected of having infectious TB, those procedures shall be conducted in one of the sputum collection booths/enclosures located in room # _____ or _____ [list room #s]. Sputum collection booths or other local exhaust devices used to prevent spread of TB shall be ventilated appropriately. See Section 6 for ventilation requirements.

(7) Most patients with infectious TB can be treated as outpatients, since close contacts have already been exposed and treatment rapidly reduces infectivity. Patients with active TB should receive directly observed therapy, whenever possible, to insure compliance with recommended treatment. Hospitalization may be indicated if the patient has other medical problems, or if there are problems in initiating directly observed therapy as an outpatient. Treatment for active tuberculosis greatly reduces the infectivity over a two to three week period. Use of masks can be discontinued when the patient has had three sputa negative or smear for AFB collected on three different days.

C. Isolation for Infectious Inpatient With TB.

Any inpatient suspected or known to have infectious TB shall be placed in AFB isolation in a private room. The room shall meet the CDC criteria for AFB isolation rooms. See Section 6 for AFB isolation room requirements.

The following rooms are designated as AFB isolation rooms [list ward and room #s].

_____ ward, rooms _ , and ___.
_____ ward, rooms _ , -, and ___
_____ ward; rooms _ , -, and ___.
_____ ward, rooms _ , -, and ___.

AFB isolation practices shall, at a minimum, include the following:

(1) Patients who are placed in AFB isolation shall be educated about the transmission of TB and the reasons for TB isolation. They shall be taught to cover their mouth and nose with a tissue when coughing or sneezing, even while in the TB isolation room.

(2) Patients in AFB isolation shall remain in the isolation room with the door closed whenever possible. Diagnostic and treatment procedures shall be performed in the isolation room whenever possible to avoid transportation of the patient throughout the institution. If a patient who may have infectious TB must be transported outside the TB isolation room for a medically essential procedure that cannot be done in the room, he/she shall wear a surgical mask covering the mouth and nose (unless the medical condition prohibits use of a mask). Procedures should be scheduled at a time when they can be performed rapidly and when waiting areas are less crowded.

(3) Efforts should be made to facilitate patient adherence to TB isolation measures, such as staying in the room. Such efforts might include the use of incentives, such as providing telephones, televisions, VCRs, or radios in the room.

(4) The number of persons entering the AFB isolation room shall be kept to a minimum.

(5) AFB isolation rooms should be prioritized to be used for patients with conditions requiring respiratory isolation with TB being a top priority.

(6) When high risk procedures (sputum induction, administration of aerosolized medication, etc.) are conducted on patients known or suspected of having

infectious TB those procedures shall be conducted in one of the sputum collection booths/enclosures located in room # _____ or _____ [list room #s]. See Section 6 for ventilation requirements associated with use of booths/enclosures.

(7) Rooms occupied by a highly suspect or known active TB patient shall have a sign posted at the door reading "AFB Isolation", "HEPA Respirator Required For Entry".

(8) AFB isolation rooms shall be checked periodically for negative air pressure and direction of air flow when occupied by a patient with known or suspected to have infectious TB. Checking of the negative air pressure can be discontinued when AFB isolation is discontinued.

(9) AFB isolation is discontinued only when the patient is on effective therapy, is improving clinically, and the sputum smear is negative for AFB for three consecutive days or, the diagnosis of TB has been ruled out.

(10) Because of the need for isolation procedures, patients with tuberculosis feel ostracized and may not comply with recommended therapy. Special efforts must be made to educate patients them about the solation requirements and to reassure them that they will likely be cured of their disease, if they comply with-the recommended treatment.

(11) The following inpatient facilities within the [name] Area have been identified as meeting the OSHA standards for treatment of contagious TB patients (list available IHS and non-IHS referral hospitals)..

_____

_____

_____

D. Environmenta1/Engineering Control

Environmental/engineering controls are used to reduce or eliminate TB droplet nuclei in the air. Ventilation systems for health care facilities shall be designed, and modified when necessary, by ventilation engineers in collaboration with infection control and occupational health staff.

The IHS Division of Facility Planning and Construction (DFPC) provides guidance on the design and operation of health care facilities. The IHS "Health Facilities Planning Manual" shall be used when new facilities are built or when existing facilities are renovated to ensure ventilation requirements are met.

Engineering controls designed to reduce or eliminate TB droplet nuclei in the air include:

(1) Local Exhaust Ventilation - booths/tents/hoods

The booth or enclosure shall maintain negative pressure in relation to the surrounding room or area. It shall have a minimum of 20 air changes per hour (ACH), and air exhausted from the booth or enclosure shall be directed to the outside of the building, away from air-intake vents, people, and animals. Alternatively, the air may be HEPA filtered prior to recirculation.

a. Air Flow Direction/Pressure Differential

The booth/hood/tent exhaust fan shall be located on the discharge side of the HEPA filter. This will maintain negative 'pressure in the booth with respect to adjacent areas.

b. **Exhaust Time Prior to re-use/cleaning.**

Booths, tents, or hoods used for cough inducing treatments shall be equipped with exhaust fans that have sufficient air flow capacity to remove greater than 99 percent of airborne particles during the time interval between the departure of one patient and the arrival of the next or before cleaning or maintenance activities are performed on the unit. A minimum of _____ [clearance time to be determined by an Industrial Hygienist or other qualified individual] minutes shall be allowed between patients or before cleaning/maintenance of the unit. Staff who enter the booth/enclosure prior to this clearance time shall be required to use a HEPA respirator.

(2) Negative Pressure Rooms (Outpatient/TB Treatment Rooms;.

a. **Air Flow Direction/Pressure Differential**

Outpatient used to examine or treat suspected or confirmed TB patients shall maintain a negative pressure in relation to-surrounding rooms. The pressure differential shall be at least 0.001 inches of water, measure at the base of the room door. [To achieve negative pressure, the ventilation system shall exhaust 10% or 50 cubic feet per minute more air, whichever is greater, than the amount of air supplied to the room.]

b. Minimum Chancres per Hour

These rooms shall have a minumum of six ACH in existing facilities, and at least twelve ACH in newly constructed or renovated rooms. Exhaust from the rooms shall be directed to the outside of the building, away from air-intake vents, people, and animals, or be HEPA filtered prior to recirculation.

(3) Isolation Rooms Inpatient Only

a. Air Flow Direction/Pressure Differential

The ventilation system shall be designed and balanced to provide air flow patterns from hallways/adjacent areas to the isolation room. A pressure differential of 0.001 inch of water, measured at the base of the room door is required.

Negative pressure shall be achieved by balancing the room supply and exhaust flows by setting the exhaust flow to a value 10 percent (but no less than 1,415,815 cubic centimeters (50 cubic feet) per minute (cfm)) greater than the supply. Negative pressure in a room can be altered by small changes in the ventilation system operation, or by the opening and closing of the isolation room, corridor doors, or windows. It is, therefore, essential that once an operating configuration has been established, all doors and windows remain appropriately closed in both the isolation room and other areas, except when needed to enter or leave an area.

b. **Minimum Air Changes per Hour**

These rooms shall have a minumum of six ACH in existing facilities, and at least twelve ACH in newly constructed or renovated rooms. Exhaust from the rooms shall be directed to the outside of the building, away from air-intake vents, people, and animals, or be HEPA filtered prior to recirculation.

c. **Private Rooms**.

Rooms used for AFB isolation shall be single-patient rooms with negative pressure relative to the corridor or other areas connected to the room. Doors between the isolation room and other areas shall remain closed except for entry or egress.

Toilet, bathtub (or shower), and hand washing facilities are required for each isolation room. These shall be arranged to permit access from the bed area without the need to enter or pass through the work area of the vestibule or anteroom.

d. Anterooms.

If provided, anteroom ventilation systems shall be designed and balanced to provide air flow patterns from hallways/adjacent areas to the anteroom and from the anteroom to the isolation room. A pressure differential of 0.001 inch of water, measured at the base of the doors, is the minimum acceptable levels from the hallway/adjacent areas to the anteroom and from the anteroom to the isolation room. A single anteroom may serve more than one isolation room.

Negative pressure shall be achieved by balancing the room supply and exhaust flows by setting the exhaust flow to a value 10 percent (but no less than 50 cfm) greater than the supply.

The anteroom shall be equipped with both a supply and exhaust vent. A minimum of 10 ACH shall be provided to the anteroom.

Alternates for Negative Pressure

Note: [Recirculation of HEPA filtered air in a" room can be achieved by.(l) recirculation of air exhausted from the room into a duct, filtered with an in-duct HEPA filter, and returned to the room ***or*** (2) in-room wall-mounted or portable HEPA filters. Room recirculation will permit higher air flow rates than can be normally achieved with general ventilation, since the air does not have to be conditioned, other than filtered. Effectiveness is dependent upon all the air in the room circulating through the HEPA filter, which can be difficult to achieve and evaluate. Portable HEPA filtration units may be considered for areas where there is no general ventilation system or where the system is incapable of providing adequate air flow.

If these units are used, caution should be exercised to assure that they can recirculate all or nearly all of the room air through the HEPA filter. Portable HEPA filtration units have not been evaluated adequately to determine their role in TB exposure control programs. Therefore, these units should not substitute for other, more established measures, except for short-term intervention while other engineering controls are being implemented.]

(4) Dilution Ventilation.

Dilution ventilation reduces the concentration of contaminants in a room by supplying air that does not contain those contaminants. The supply air mixes with and then displaces some of the contaminated room air, which is subsequently removed from the room by the exhaust system. Dilution ventilation can be achieved using two types of systems; single pass or recirculating systems.

a. Air Flow Direction/Pressure Differential

General ventilation systems shall be designed to (1) prevent stagnation of the air and (2) prevent short circuiting of the supply to the exhaust. The general ventilation system shall be designed and balanced to provide air flow patterns from more clean to less clean areas, such as from hallways to treatment rooms or

corridors to patient rooms. The direction of air flow is controlled by creating a lower pressure in the area into which flow is desired (a minimum of 0.001 inches of water). Negative pressure is attained by exhausting air from the area at a higher rate than it is being supplied.

b. The ACH and recirculation

The IHS "Health Facilities Planning Manual" will be followed concerning the minimum ACH and percentage of recirculation for all general use areas.

(5) Direct Discharge & HEPA Filtration

The air discharged from AFB isolation rooms, anterooms, negative pressure TB treatment rooms, booths, tents, and hoods shall be exhausted directly to the outside of the building, away from air-intake vents, people, and animals, in accordance with federal, state, and local regulations concerning environmental discharges.

Note: [Design guidelines for proper placement can be found in the 1989 ASHRAE Fundamentals Handbook. If direct exhaust to the outside is impossible, air from isolation rooms, booths, tents, and hoods should only be exhausted within the facility through Properly designed, installed, and maintained HEPA As an additional safety measure air may be discharged to the outside through HEPA filters to preclude reentry of air containing infectious droplet nuclei into the ventilation supply. This is especially desirable if the exhaust discharge cannot be extended to the roof.)

(6) Periodic Maintenance/Testing of Controls

The _____ [list the department responsible] shall develop, implement, and document a maintenance program that will ensure that the environmental/engineering controls implemented to reduce exposure to TB operate properly. The maintenance program shall include as a minimum the following items:

a. Initial and thereafter quarterly evaluation of each isolation room, anteroom, booth, tent, or

hood/enclosure for ACH, and direction and velocity of air flow into the space.

b. Periodic testing, when in use, of each isolation room, anteroom, booth, tent, or hood/enclosure for negative pressure.

C. Initial determination of the location of exhaust discharge to ensure the exhaust from isolation rooms, anterooms, booths, tents, and hoods/enclosures is not discharged near an intake source or area where the public or employees will be exposed.

d. Monitoring of the equipment and HEPA filtering apparatus as recommended by the manufacturer. A quantitative leakage and filter performance test using the dioctal. phthalate (DOP) penetration test shall be performed at the initial installationof a HEPA filter and whenever the HEPA filter is changed or moved. A manometer or other pressure sensing device shall be installed in the filter system to provide an accurate means of objectively determining the need for filter replacement. Pressure drop characteristics of the filter are supplied by the manufacturer. Installation shall allow for maintenance without contaminating the delivery system or the area served. The "bag in, bag out" method used for changing filters in systems containing carcinogens shall be used. Because of the potential risk of infection to staff who perform this maintenance-, it shall be performed only by personnel who are adequately trained. Appropriate respiratory protection shall be worn during maintenance and testing. In addition, filter housing and ducts leading to the housing shall be clearly marked "Contaminated Air".

E. Respiratory Protection

All HCWs who enter a TB isolation room, booth; or other space (including vehicles used to transport patients) where known or suspected TB patients are receiving care shall be supplied with and wear a particulate respirator that meets recommended performance criteria and requirements of CDC and OSHA. The respiratory protection program shall comply with the requirements set forth in 29 CFR 1910.134.

(1) Employee Requirements

All HCWs required to use respiratory protection shall be included in this program. The respiratory protection program shall, at a minimum, include:

a. Assignment of responsibility: Supervisory responsibility for the respiratory protection program shall be assigned to _____ [list the person/position responsible].

b. Procedures: Written procedures shall contain information on all aspects of the respiratory protection program.

c. Medical Screening: The HCWs shall not be assigned a task requiring use of respirators. unless they are physically able to do the work while wearing the respirator. The HCWs shall be screened for pertinent medical conditions upon employment and periodically rescreened.

d. Training: Respirator wearers and supervisors shall receive training in the reasons for the need for wearing their respirator and the potential risks of not doing so. This training shall also include an explanation of the 'operation, capabilities, and limitations of the respirator provided.

e. Face-Seal Fit Testing and Fit Checking: The HCWs shall undergo fit testing to identify a respirator with an adequate fit for that HCW. The HCW shall receive fitting instructions including demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly. The HCW shall be instructed to check the face piece fit before each use.

f. Respirator Inspection, Cleaning, Maintenance, and Storage: Respirator maintenance shall be made an integral part of the overall respirator program. Manufacturers' instructions for inspection, cleaning, and maintenance of respirators shall be followed to ensure that the respirator continues to function properly. The respirators shall be stored in accordance with

CRF 1910.134 (B) (6) in a convenient, clean, and sanitary location.

g. Periodic Evaluation of the Personal Respiratory Protection Program: The program shall be 'completely evaluated at least annually, and both the written operating procedures and program administration shall be modified as necessary based on the results. Elements of the program that shall be evaluated include work practices and acceptance of respirators, including comfort and interference with duties. The evaluation of the use and maintenance of respirators, shall be included as a part of the facility hazard surveillance program.

(2) Respira~~tor Perf~~orman~~ce Criteria~~

Respiratory protective devices used by employees for TB shall meet the OSHA respiratory protection standard.

Note: Respirators with HEPA filters are the only currently available certified respirators that meet the OSHA standard. The National Institute of Occupational Safety and Health is in the process of creating a certification standard for respirators with a 95% efficiency for removal of particles 1u or smaller. When the certification standard is complete, the 95% respirators should be used.

(3) **Indicators For Use**

Appropriate respiratory protection shall be worn by persons potentially exposed to TB in settings where administrative and engineering controls may not provide adequate protection. Such settings include TB isolation rooms and rooms in which patients who may have infectious TB are undergoing cough inducing or aerosol generating procedures (irrigation of tuberculous abscesses, performing bronchoscopies, sputum induction, etc.)., and the transport of patients who may have infectious TB in emergency transport vehicles. Every attempt will be made to prevent occupational exposure using engineering or administrative controls before requiring the use of respirators.

(4) Patients.

Patients with active TB or those suspected to have active TB shall be required to wear a surgical mask while in the facility, unless they are in a TB isolation room.

(5) **Visitors**.

The number of visitors allowed shall be kept to an absolute minimum during the time period. when the patient is considered infectious. Individuals who visit a 'patient with active TB shall be notified that they should wear respiratory protection during the time they are in the patient's room. At a minimum surgical masks shall be available for use by those individuals visiting patients with active TB.

F. Cough-Inducing Procedures

Procedures that involve instrumentation of the lower respiratory tract or induce cough 'may increase the probability of droplet nuclei being expelled into the air. These cough inducing procedures include endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments, and bronchoscopy. The following methods shall be followed when cough inducing procedures are conducted on individuals that have or are suspected of having TB:

(1) Cough inducing procedures shall be performed on patients who may have infectious TB using local exhaust ventilation devices (e.g., booths or special enclosures) or in a room that meets the ventilation requirements for TB isolation.

(2) Patients shall remain in the isolation room or enclosure and not return to common waiting areas until coughing subsides. They shall be given tissues and instructed to cover their mouth and nose when coughing or sneezing.

(3) Before the booth, enclosure, or room is used for another patient, _____ [clearance time to be determined by an Industrial Hygienist or other qualified individual] minutes shall be allowed to pass so that any droplet nuclei that have been expelled into the air are removed.

G. Staff Training and Education

All HCWs shall receive education about TB that 'is appropriate to their job category. Training shall be conducted before initial assignment and subsequently on a periodic basis. Although the level and detail of this education may vary according to job description, the following information should be included in the education of all HCWs:

(1) **The** basic concepts of TB transmission, pathogenesis, and diagnosis, including the difference between latent TB infection and active TB disease, the signs and symptoms of TB, and the possibility of reactivation in persons with a positive PPD test.

(2) The potential for occupational exposure, the prevalence of TB in the community and facility, the ability of the facility to appropriately isolate patients with active TB, and situations with increased risk of exposure to TB.

(3) The principles and practices of infection control that reduce the risk of transmission of TB.

(4) The purpose of a PPD testing program.

(5) The principles of preventive therapy for latent TB infection. Indications, use, and effectiveness, including the potential adverse effects of the drugs.

(6) The responsibility of the HCW to seek medical evaluation promptly if symptoms develop that may be due to TB.

(7) The principles of drug therapy for active TB.

(8) The importance of notifying the facility if diagnosed with active TB so appropriate contact investigation can be instituted.

(9) The responsibilities of the facility to maintain the confidentiality of HCWs diagnosed with **TB** while assuring appropriate therapy is received.

(10) The higher risk posed by TB to individuals with HIV infection or other causes of severely impaired cell-mediated immunity.

(11) The potential* development of cutaneous anergy as immune function measured by CD4 + T-lymphocyte counts, declines.

(12) The facility's policy on voluntary work reassignment options for immunocompromised HCWs should be explained.

H. The HCWs Counseling and Screening

Individuals with HIV or others with impaired cell-mediated immunity are at a higher risk of developing active TB. Counseling of these employees shall include information on the following:

(1) More frequent and rapid development of clinical TB after infection. Because of the increased risk of rapid progression from latent TB infection to active TB in HIV-positive or otherwise severely immunocompromised persons, all HCWs should know if they have a medical condition or are receiving a medical treatment that may lead to severely impaired cell-mediated immunity.

(2) High mortality rate associated with MDR-TB in this group. Among patients with active MDR-TB, the case-fatality rate was extraordinarily high (72 to 89 percent). Of eight HCWs from these hospitals who developed active MDR-TB, four with known HIV infection died.

(3) The voluntary reassignment program for immunocompromised HCWs. Immunocompromised HCWS shall be referred to an employee health professional who can counsel the employee on an individual basis regarding his/her risk of TB. Upon the request of the immunocompromised HCW, the facility shall offer, but not compel, a work setting in which the HCW would have the lowest possible risk of occupational exposure TB. Information provided by HCWs regarding their immune status shall be treated confidentially.

I. Decontamination

(1) Environmental Surfaces

The same routine daily cleaning procedures used in other rooms in the facility shall be used to clean

rooms of patients who are on AFB isolation. Personnel cleaning the room should follow AFB isolation practices.

(2) Equipment Used On Patients.

Equipment used on patients with TB is unlikely to be involved in the transmission of-the organism, although transmission by contaminated bronchoscopes has been demonstrated. The policies and procedures developed by the infection control program for cleaning, disinfecting, or sterilizing patient-care equipment should be followed.

J. Coordination of Efforts With Public Health Department

Results of all AFB positive sputum smears, cultures positive for TB, and drug-susceptibility results on TB isolates shall be forwarded to the _____ [list the name of the health department to be notified] health department as soon as they become available, in accordance with State and local laws and regulations.

_____ [list the person/position responsible for follow up activities] shall coordinate efforts with State, tribal and local health departments to perform appropriate contact investigations on patients and HCWs with active TB. A discharge plan coordinated with the patient or HCW, the health department, and the inpatient facility shall be implemented.

K. Specific Settings or Circumstances.

(1) Operating rooms.

Elective operative procedures on patients with TB will be delayed until the patient is no longer infectious. If procedures must be performed, they will be done in operating rooms with anterooms if possible. The doors to the operating room shall be closed and traffic in and out of the room shall be kept to a minimum. Attempts will be made to perform the procedure at a time when other patients are not present in the operative suite and when a minimum number of personnel are present.

The patient will be monitored during recovery in the specify the location of the room, e.g. ICU isolation room meeting TB isolation room ventilation recommendations.

Personnel present when operative procedures are performed on patients who may have infectious TB shall wear respiratory protection approved for TB exposure rather than standard surgical masks alone, A surgical mask (or equivalent) shall be used to cover the exhalation valve of the HEPA respirator.

(2) Autopsy rooms (Inpatient Only)

Due to the probability of the presence of infectious aerosols, autopsy rooms shall be at negative pressure with respect to adjacent areas, with room air exhausted directly to the outside of the building. There shall be no recirculation of air exhausted from autopsy rooms. ASHRAE recommends that autopsy rooms have ventilation that provides 12 total air changes per hour. Respiratory protection approved for TB exposure shall be worn by personnel while performing autopsies on patients were suspected of having TB.

(3) Emergency medical services

When emergency medical response personnel or others must transport patients with confirmed or suspected active TB, a surgical mask shall be placed on the patient, if possible. The HCW shall wear a respirator approved for TB exposure in emergency transport situations and vehicles.

(4) Laboratories

Laboratories processing specimens for mycobacterial studies (e.g., 'AFB smears and cultures) shall conform to.CDC criteria.

(5) Dental Offices -

Patients with history and symptoms suggestive of active TB shall be promptly referred for evaluation for possible infectiousness. If the patient is determined to have infectious TB, elective dental treatment should be deferred until the patient is no longer infectious.

If dental procedures must be performed on a patient who has, or is strongly suspected of having infectious TB, AFB isolation practices shall be

implemented. Dental procedures shall be done in operatories properly designed for used of nitrous oxide analgesia, i.e. an enclosed room with a non-recirculating ventilation. system. These rooms should have at least 10 ACH in existing facilities and 12 ACH in new construction. The doors to the operatories shall be closed and traffic in and out of the room shall be kept to a minimum. Attempts will be made to perform the procedure at a time when other patients are not present in the operative suite and when a minimum number of personnel are present. The patient will be monitored during recovery in an individual room meeting AFB isolation room ventilation recommendations. Dental HCWs shall *use* respiratory protection approved for TB exposure while performing procedures on such patients.

(6) Home health services

Precautions may be necessary for HCWs visiting the home of patients with suspected or confirmed infectious TB. The precautions include instructing the patient to cover his/her mouth and nose with a tissue when coughing or sneezing, offering the patient a surgical mask, and HCWs wearing respiratory protection approved for TB exposure during high risk procedures such as entering the patient's room. Cough inducing procedures will not be performed on patients with infectious TB in the home. Home health care personnel will assist in preventing TB transmission by educating the patient about the importance of taking medications as prescribed and by administering directly observed therapy.

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