INFORMATION MEMORANDUM 94-X-93 (REV.)

TO: Managers, Supervisors and Field Personnel

FROM: William M. Lybrand

DATE: July 3, 1996

SUBJECT: Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis

This memorandum provides background information and state enforcement policy and procedures for inspections concerning occupational exposure to tuberculosis.

These guidelines are based on Federal OSHA policy and current CDC recommendations.

A. Definitions. For a complete list of definitions applicable to tuberculosis please refer to the list of definitions in the 1994 CDC guidelines found in Appendix A.
B. Background. Since 1985, the incidence of tuberculosis (TB) in the general U.S. population has increased approximately 14 percent, reversing a 30-year downward trend. In 1993, 25,313 new cases of TB were reported in the United States. Increases in the incidence of TB have been observed in some geographic areas; these increases are related partially to the high risk for TB among immunosuppresed persons, particularly those infected with human immunodeficiency virus (HIV). Other factors (e.g., socioeconomic) have also contributed to these increases. Outbreaks have occurred in hospitals, correctional institutions, homeless shelters, nursing homes, and residential care facilities for AIDS patients. During 1994 and 1995 there has been a decrease in the number of TB cases in the United States that has likely been due to increased awareness and efforts in the prevention and control of TB, including the implementation of TB control measures recommended by the CDC and required by OSHA.

   Recently, drug resistant strains of *M. tuberculosis* have become a serious concern and cases of multi-drug-resistant (MDR) TB have occurred in forty states. In a recent New York City study, 33% of cases had organisms resistant to the two most effective drugs available for treating and disease.

   When organisms are resistant to both drugs, the course of the treatment increases from 6 months to 18-24 months, and the cure rate decreases from 100% to 60% or less.

   In a 1992 American Hospital Association survey/CDC survey, 90 of 729 (13%) respondents reported nosocomial TB transmission to health care workers. More than 80% of those facilities experienced TB skin test conversions among workers. More than 100 cases of active TB disease in health care workers were known to CDC and reported to Congress by Dr. William Roper in the Spring of 1993.

Twelve (12) health care workers have died. Nationwide, at least several hundred employees have become infected and required medical treatment after workplace exposure to TB. In general, persons who become infected with TB have approximately a 10% risk for developing active TB in their lifetimes.

In 1988 and 1989, South Carolina ranked number 5 for new TB cases in the U.S. and has been in the top 10 states for the highest TB case rate, except for 2 years, 1979 and 1991. The number of new cases annually in S.C. has declined from 502 cases in 1989 to 387 cases in 1992. South Carolina's current rate is 9.58 (per 100,000) with 387 cases reported in 1995. Multi-resistant TB cases have been identified in South Carolina with the highest case rates in the Pee Dee and Coastal areas, and the lowest case rates in the upstate.

M. tuberculosis is carried through the air in tiny infectious droplet nuclei of 1 to 5 microns in diameter. These droplets may be generated when a person with pulmonary and laryngeal TB disease coughs, speaks, sings, sneezes, or spits. When inhaled by susceptible persons, the mycobacteria in these droplets may become established in the lungs and, in some cases, spread throughout the body. After an interval of months, years, or even decades, the initial infection may then progress to clinical illness (i.e., tuberculosis disease). Transmission of TB is most likely to occur from persons with pulmonary or laryngeal TB that are not on effective anti-TB therapy and who have not been placed in respiratory isolation.

In occupational health care settings, where patients with TB are seen, workers exposed to tuberculosis droplet nuclei are at increased risk of infection with exposure to TB. Certain high-risk medical procedures that are cough-inducing or aerosol generating can further increase the risk of infection in health care workers.

The employer's obligations are those set forth in the Occupational Safety and Health Act (OSH Act) of 1970. Recommendations for preventing the transmission of TB for health care settings were originally established with the 1990 CDC Guidelines. In October, of 1994, those guidelines were revised and published (Appendix A). The new guidelines emphasize the control of TB through an effective TB infection control program. Under these guidelines the control of TB is to be accomplished through the early identification, isolation, and treatment of persons with TB, use of engineering and administrative procedures to reduce the risk of exposure, and through the use of respiratory protection. OSHA believes these guidelines reflect an industry recognition of the hazard as well as appropriate, widely recognized, and accepted standards of practice to be followed by employers in carrying out their responsibilities under the OSH Act.

C. Inspection Scheduling and Scope

1. The evaluation of occupational exposure to TB shall be conducted in response to employee complaints, related fatality/catastrophe, or as part of all industrial hygiene inspections conducted in workplaces where the CDC has identified

workers as having a greater incidence of TB infection than in the general population. The degree of risk of occupational exposure of a worker to TB will vary based on a number of factors discussed in detail by the CDC (Appendix A). These workplaces have been the subject of reports issued by the CDC which provide recommendations for the control of tuberculosis. Specifically, these workplaces are as follows:

a. health care facilities
b. correctional institutions
c. long-term care facilities for the elderly
d. homeless shelters
e. drug treatment centers

Note: Health care facilities include hospitals where patients with confirmed or suspected TB are treated or to which they are transported. Coverage of non-hospital health care settings (i.e., doctors' offices, clinics, etc.) includes only personnel present during the performance of high hazard procedures on suspected or active TB patients. Dental health care personnel are covered by the directive only if they treat suspected or active patients in a hospital or correctional facility.

Homeless shelters – due to a variety of circumstances, the control of TB in homeless shelters presents unique problems for the protection of workers. Shelters must establish protocols that provide for rapid early identification followed by immediate transfer of suspected cases if the shelters have elected not to treat these patients.

2. All inspections in these workplaces shall include a review of the employer's plans for employee TB protection, if any. Such plans may include the infection control program, respiratory protection and skin testing. Employee interviews and site observations are an integral part of the process evaluation.

D. Inspection Procedures.

1. Health care facilities generally have internal infection control and employee health programs. This function may be performed by a team or individual. Upon entry, the inspector shall request the presence of the infection control director and employee occupational health professional responsible for occupational health hazard control. Other individuals who will be responsible for providing records pertinent to the inspection may include: training director, facilities engineer, director of nursing, etc.

2. The inspector shall establish whether or not the facility has had a suspected or confirmed TB case within the previous six (6) months from the opening conference to determine coverage under the OSH Act. This determination

may be based upon interviews and, in a hospital, a review of the infection control data.

3. If the facility has had a suspected or confirmed TB case within the previous six months, the inspector shall proceed with the TB portion of the inspection. The inspector shall verify implementation of the employer's plans for TB protection through employee interviews and direct observation where feasible. Professional judgment shall be used to identify which areas of a facility must be inspected during the walkthrough (e.g., emergency rooms, respiratory therapy areas, bronchoscopy suites, and morgue). After review of the facility plans for worker TB protection, employee interviews combined with an inspection of appropriate areas of the facility shall be used to determine compliance.

4. Inspectors shall check the air-flow for the respiratory isolation rooms, using a velometer, during the walk through of the facility.

E. Compliance Officer Protection

1. Inspectors shall not enter occupied respiratory isolation [AFB (acid fast bacilli)] rooms to evaluate compliance. Photographs or video taping, where practical, shall be used for case documentation. Under no circumstances shall photographing or videotaping of patients be done. Inspectors must take all necessary precautions to assure and protect patient confidentiality.

2. Inspectors normally shall establish the existence of hazards and adequacy of work practices through employee interviews and shall observe them in a manner which prevents exposure.

3. Inspectors who conduct TB inspections shall have been offered the TB skin tests. Inspectors exposed to an individual(s) with active infectious TB shall receive a follow-up examination and follow appropriate guidelines in Appendix A.

   Note: A "TB Skin Test" means the intradermal injection (Mantoux Method) of tuberculin antigen (usually PPD) with subsequent measurement of any reaction by designated, trained personnel.

F. Citation Policy.

1. The following requirements apply when citing hazards found in target workplaces. Employers must comply with the provisions of these requirements whenever an employee may be occupationally exposed to TB:

   SCRR 71-1.12A -- General Duty Clause

1910.134 -- Respiratory Protection

1910.145 -- Accident Prevention Signs and Tags

1910.1020 -- Access to Employee Exposure and Medical Records

29 CFR 1904 -- Recording and Reporting Occupational Injuries & Illness

G. Violations. All elements in this section must be addressed to ensure adequate protection of employees from TB hazards. Violations of these OSHA requirements will normally be classified as serious.

1. General Duty Clause – SCRR 71-112A. SCRR 71-112A provides: "Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely; to cause death or serious physical harm to his employees."

   a. General Duty Clause citations must meet the requirements outlined in the OSHA Field Inspection Reference Manual, and shall be issued only when there is no standard that applies to the particular hazard. The hazard, not the absence of a particular means of abatement, is the basis for a general duty clause citation. All applicable abatement methods identified as correcting the same hazard shall be issued under a single general duty citation.

   b. Recognition, for purposes of citing the general duty clause is shown by the CDC Guidelines for the types of exposures detailed below because the CDC is an acknowledged body of experts familiar with the hazard.

   c. Citations shall be issued to employers with employees working in one of the workplaces where the CDC has identified workers as having a higher incidence of TB infection than the general population, when the employees are not provided appropriate protection and who have exposure as defined below:

      1. Exposure to the exhaled air of an individual with suspected or confirmed pulmonary TB disease, or

         Note: A suspected case is one in which the facility has identified an individual as having symptoms consistent with TB. The CDC has identified the symptoms to be: productive cough, coughing up blood, weight loss, loss of appetite, lethargy/weakness, night sweats, or fever.

      2. Employee exposure without appropriate protection to a high hazard procedure performed on an individual with suspected or confirmed infectious TB disease and which has the potential to generate

infectious airborne droplet nuclei. Examples of high hazard procedures include aerosolized medication treatment, bronchoscopy, sputum induction, endotracheal intubation and suctioning procedures, emergency dental, endoscopic procedures, and autopsies conducted in hospitals.

d. If a citation is justified, the "as follows" should be written as shown in the example below:

Employer knew or should have known that employees in the (location) were exposed to hazards of being infected with tuberculosis through contact with (patients, inmates, clients, etc.) who were or may be infected with TB in that employees were exposed while (give specific job duty). A feasible and useful means of abatement, among others, is the development and enforcement of a written TB program which includes as a minimum the following elements: [list abatement methods].

e. The following are examples of feasible and useful abatement methods, which must be implemented to abate the hazard. Deficiencies found in any category can result in the continued existence of a serious hazard and may, therefore, allow citation under the general duty clause.

1. Early Identification of Patient/Client. The employer shall implement a protocol for the early identification of individuals with active TB. See Appendix A.

2. Medical Surveillance:

a. Initial Exams. The employer, in covered workplaces, shall offer TB skin tests (at no cost to the employees) to all current potentially exposed employees and to all new employees prior to exposure. A two-step baseline shall be used for new employees who have an initially negative PPD test result and who have not had a documented negative TB skin test result during the preceding 12 months (see Appendix A). TB skin tests shall be offered at a time and location convenient to workers. Follow-up and treatment evaluations are also to be offered at no cost to the workers.

Note: The giving, reading and interpretation of the TB skin tests shall be performed by a qualified individual as described in the CDC Guidelines.

b. Periodic Evaluations. TB skin testing shall be conducted every three (3) months for workers in high risk categories, every six (6) months for workers in intermediate risk categories, and annually for low risk personnel (The CDC has defined the criteria for high, intermediate,

and low risk categories, see Appendix A). Workers with a documented positive TB skin test who have received treatment for disease or preventive therapy for infection are exempt from the TB skin test but must be informed periodically about the symptoms of TB and the need for immediate evaluation of any pulmonary symptoms suggestive of TB by a physician or trained health care provider to determine if symptoms of TB disease have developed.

Note: If the facility has not completed a risk assessment, the inspector shall review the TB related records to establish required testing frequencies for the facility and areas of the facility.

c. Reassessment Following Exposure or Change in Health. Workers who experience exposure to an individual with suspected or confirmed infectious TB, for whom infection control precautions have not been taken, shall be managed according to CDC recommendations (Appendix A). An employee who develops symptoms of TB disease shall be immediately according to the CDC Guidelines.

3. Case Management of Infected Employees shall include the following:

   a. Protocol for New Converters. Conversion to a positive TB skin test shall be followed as soon as possible, by appropriate physical, laboratory, and radiographic evaluations to determine whether the employee has infectious TB disease, (see Appendix A).

   b. Work Restrictions for Infectious Employees. (See Appendix A).

4. Worker Education and Training. Training and information to ensure employee knowledge of such issues as the mode of TB transmission, it's signs and symptoms, medical surveillance and therapy, and site specific protocols including the purpose and proper use of controls shall be provided to all current employees and to new workers upon hiring. Training should be repeated as needed based on the risk assessment, but at least annually, (see Appendix A).

   Workers shall be trained to recognize, and report to a designated person, any patients or clients with symptoms suggestive of infectious TB and instructed on the post exposure protocols to be followed in the event of an exposure incident, (See Appendix A).

5. Engineering Controls**.** The use of each control measure must be based on its ability to abate the hazard.

   a. Individuals with suspected or confirmed infectious TB disease must be placed in a respiratory acid-fast bacilli (AFB) isolation room. High

hazard procedures on individuals with suspected or confirmed infectious TB disease must be performed in AFB treatment rooms, AFB isolation rooms, booths, and/or hoods. AFB isolation refers to a negative pressure room or an area that exhausts room air directly outside or through HEPA filters if recirculation is unavoidable.

b. Isolation and treatment rooms in use by individuals with suspected or confirmed infectious TB disease shall be kept under negative pressure to induce airflow into the room from all surrounding areas (e.g., corridors, ceiling plenums, plumbing chases, etc.). (See Appendix A, supplement No. 3).

   Note: The employer must assure that AFB isolation rooms are maintained under negative pressure. At a minimum, the employer must use nonirritating smoke trails or some other indicator to demonstrate that direction of airflow is from the corridor into the isolation/treatment room with the door closed. If an anteroom exists, direction of airflow must be demonstrated at the inner door between the isolation/treatment room and the anteroom. (See Appendix B).

c. Air exhausted from AFB isolation or treatment rooms must be safely exhausted directly outside and not recirculated into the general ventilation system. (See Appendix A, Supplement No. 3).

   In circumstances where recirculation is unavoidable, HEPA filters must be installed in the duct system from the room to the general ventilation system. (See Appendix A, Supplement No. 3). For these HEPA filters, a regularly scheduled monitoring program to demonstrate as-installed effectiveness should include; 1) recognized field test method, 2) acceptance criteria, and 3) testing frequencies (see Appendix A, Supplement No. 3). The air handling system should be appropriately marked with a TB warning where maintenance personnel would have access to the duct work, fans, or filters for maintenance or repair activities.

d. In order to avoid leakage, all potentially contaminated air which is ducted through the facility must be kept under negative pressure until it is discharged safely outside (i.e., away from occupied areas and air intakes), or

e. The air from isolation and treatment rooms must be decontaminated by a recognized process (e.g., HEPA filter) before being recirculated back to the isolation/treatment room. The use of UV radiation as the sole means of decontamination shall not be used. The CDC Guidelines allow the use of UV in waiting rooms, emergency rooms, corridors,

and the like where patients with undiagnosed TB could potentially contaminate the air. (See Appendix A).

Note: The opening and closing of doors in an isolation or treatment room which is not equipped with an anteroom compromises the ability to maintain negative pressure in the room. For these rooms, the employer should utilize a combination of controls and practices to minimize spillage of contaminated air into the corridor. Recognized controls and practices include, but are not limited to: minimizing entry to the room; adjusting the hydraulic closer to slow the door movement and reduce displacement effects; adjusting doors to swing into the room where fire codes permit; avoiding placement of room exhaust intake near the door; etc.

f. If high-hazard procedures are performed with AFB isolation or treatment rooms without benefit of source control ventilation or local exhaust ventilation (e.g., hood, booth, tent, etc.), and droplets are released into the environment (e.g., coughing), then a purge time interval must be imposed during which personnel must use a respirator when entering the room. (See Appendix A).

g. Interim or supplemental ventilation units equipped with HEPA filters as described in Appendix A are acceptable.

2. Respiratory Protection – 29 CFR 1910.134(a)(2) and (b).
The standard provides in part:

"Respirators shall be provided by the employer when such equipment is necessary to protect the health of the employee. The employer shall provide the health of the employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protective program which shall include the requirement outlines in paragraph (b) of this section."

a. Requirements for a minimal acceptable program.
The 1994 CDC Guidelines specify standard performance criteria for respirators for exposure to TB. These criteria include (see Appendix A).

1. The ability to filter particles 1 μm in size in the unloaded state with a filter efficiency of >95% (i.e., filter leakage of <5%), given flow rates of up to 50L per minute.

2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of <10% (See S.C. Information

Memorandum 86 x 71 for fit test requirements of single-use respirators).

3. The ability to fit the different facial sizes and characteristics of health care workers which can usually be met by making the respirators available in at least three sizes.

4. The ability to be checked for face piece fit, in accordance with OSHA standards and good industrial hygiene practice, by health care workers each time they put on their respirator.

b. Under the new NIOSH criteria, filter materials would be tested at a flow rate of 85L/minute for penetration by particles with a median aerodynamic diameter of 0.3 μm and, if certified, would be placed in one of the following categories: Type 100 (99.7% efficient), Type 99 (99% efficient), and Type 95 (95% efficient). NIOSH has determined that these criteria, the minimally acceptable level of respiratory protection for TB is the Type 95 Respirator. The classes of these air-purifying, particulate respirators to be certified are described under 42 CFR Part 84 Subpart K. See Volume 60 of the Federal Register, page 30338 (June 8, 1995). Other than these classes of respirators, only HEPA respirator will be accepted as providing a minimal level of respirator protection (see Appendix A).

   The following respirator protection measures must be addressed:

   1. Employees wear HEPA or respirators certified under 42 CFR Part 84 Subpart K in the following circumstances:

      a. When workers enter rooms housing individuals with suspected or confirmed infectious TB.

      b. When workers are present during the performance of high hazard procedures on individuals who have suspected or confirmed infectious TB.

      c. When emergency-medical-response-personnel or others transport, in a closed vehicle, an individual with suspected or confirmed infectious TB.

      Note: if a facility chooses to use disposable respirators as part of their respiratory protection program, their reuse by the same health care worker is permitted as long as the respirator maintains it's structural and functional integrity and the filter material is not physically damaged or soiled. The facility must address the circumstances in which a disposable respirator will be considered to be contaminated and not available for reuse.

c. Compliance Officers shall cite 1910.134 (a)(2), which requires that respirators be provided when necessary to protect employee health, when no respiratory protection is provided or there is a complete lack of a respirator program. Citations shall be issued under 1910.134 (b)(11) when respirators being worn are not NIOSH-approved for tuberculosis. The appropriate sections of 1910.134 (b) shall be cited in accordance with INFORMATION MEMORANDUM 96 x 100 when there are deficiencies in the employers respiratory protection program. If a citation is warranted under 1910.134 (a)(2), the "as follows" should state:

Employee(s) in (location) were not provided with at least NIOSH approved respirator for protection against airborne Mycobacterium tuberculosis.

3. Access to Employee Medical Exposure Records:

a. A record concerning employee exposure to TB is an employee exposure record within the meaning of 1910.1020.

b. A record of TB skin test results and medical evaluations and treatment are employee medical records within the meaning of 29 CFR 1910.1020. Where known, the workers exposure record should contain a notation of the type of TB to which the employee was exposed to (e.g., multi-drug resistant TB).

c. These records shall be handled according to the South Carolina Code of Laws so that the compliance officer may determine compliance with 1910.1020.

4. Accident Prevention Signs and Tags: 1910.145.

a. In accordance with 1910.145(f)(8), a warning shall be posted outside the respiratory isolation or treatment room. 1910.145 (f)(4) requires that a signal work (i.e., "STOP", "HALT", or "NO ADMITTANCE") or a biological hazard symbol be presented as well as a major message (e.g., "special respiratory protection", "Respiratory Isolation", or "AFB Isolation"). A description of the necessary precautions, e.g., "respirators must be donned before entering". Signs shall also be posted on respiratory isolation rooms in an emergency department to refer someone to the nursing station for instructions.

b. The employer shall also use biological hazard tags on the air transport components (e.g., fans, ducts, filters) which identify TB hazards to employees associated with working on air systems that transport contaminated air (see Appendix A).

Abatement Note: Warning signs must be posted on respiratory isolation or treatment rooms stating " pulmonary isolation",

"respiratory isolation", or "AFB isolation". The sign must state specifically the precautions required to interact with those patients. Indicators on patient records or tags on corpses, printed in language or symbols easily recognized by employees are additional methods to achieve this purpose.

5. OSHA 200 Log- Injury and Illness Logs:

   a. For OSHA form 200 record keeping purposes, both tuberculosis infections (positive TB skin test) and tuberculosis disease are recordable in the high risk setting referenced in section C.1. A positive skin test for tuberculosis, even on initial (baseline) testing (except pre-employment screening) is recordable on the OSHA 200 log because there is a presumption of work-relatedness in these settings unless there is clear documentation that an outside exposure occurred.

   b. If the employee's tuberculosis infection which was entered on the OSHA 200 log progresses to tuberculosis disease during the five-year maintenance period, the original entry for the infection shall be updated to reflect the new information. Because it is difficult to determine if tuberculosis disease resulted from the source indicated by the skin test conversion or from subsequent exposures, only one case should be entered to avoid double counting.

   c. A positive TB skin test provided within two weeks of employment does not have to be recorded on the OSHA 200 forms. However, the initial test must be performed prior to any potential workplace exposure within the initial two weeks of employment.

H. Recording in the IMIS: A TB-related inspection is any health inspection conducted to investigate the presence or alleged presence of TB disease (i.e., a referral or complaint inspection).

   1. When a TB-related inspection is conducted, complete the OSHA-1 as for any inspection and enter the code "N 02 TB" in Item 42, Optional Information. Example:

Type	ID	Value
N	2	TB

   2. When an OSHA-7 is completed and the complaint alleges the presence of TB hazards, enter the code "N 02 TB" in Item 26, Optional Information.

I. Citation Review:
All proposed citations shall be approved by the Compliance Manager.

J. Effective Date:
This memorandum is effective immediately.

ATTACHMENT B

RESPIRATOR SELECTION LOGIC

OSHA has identified the appropriate minimum level of respiratory protection for occupational exposure to TB, based on the following best available information regarding the characteristics of exposure and feasibility of compliance:

- The minimum respiratory protection is a NIOSH-approved high-efficiency particulate air (HEPA) respirator.

- The employer must establish and implement a respiratory protection program in accordance wit the requirements of OSHA's respiratory protection standard, 29 CFR 1910.134.

In making the selection of respirators for protection against TB, it was necessary to consider factors which affect the performance of respirators such as filter performance, face seal leakage and fit check. These factors are as follows:

Factor #1: Identification and selection rationale of the appropriate minimum level of respiratory protection for occupational exposure to TB.

Engineering controls must be implemented to reduce the risk of exposure to TB. The selection of respirators to supplement engineering controls, is usually based on the permissible exposure limit for the air contaminant in question. There is no known safe exposure level for TB. Therefore, it is prudent to select respirators which would provide minimal margin of error since each additional inhaled TB bacillus may increase the risk of disease. The nature of work in connection with TB patients is a critical factor that must be kept in mind in selection appropriate respirators for exposure to TB. Respiratory protection requirements will be modified later if a threshold for TB exposure is established.

Since there is no established safe exposure level for TB, NIOSH recommends that hospitals use powered air-purifying respirators (PAPRs) as the minimum level of respiratory protection for exposure to TB. OSHA, however, recognizes that PAPRs may interfere with patient care, or could be infeasible for other reasons. Therefore, OSHA does not require the use of PAPRs as the minimum level of acceptable respiratory protection.

Based on the best currently available information on respirator filters and respirator characteristics, OSHA requires the use of a NIOSH-approved HEPA particulate respirator for workers in TB isolation rooms, during high hazard procedures, and involved in medical transport in closed vehicles as the minimum level of protection. In order to minimize the exposure to TB, effective fit tests and fit checks must be performed.

Quantitative or qualitative fit testing must be performed for each respirator wearer. The quantitative fit testing (QNFT) is the most reliable fit testing method. (OSHA has accepted several qualitative fit [QLFT] agents such as isoamyl acetate, irritant fume, and sodium saccharin. The mass median aerodynamic diameter for the saccharin aerosol is 3 μm and the irritant fume is in the submicrometer range. The irritant fume QLFT is considered to be the more reliable test agent since the saccharin QLFT is dependent of the subjective response of the test subject to the taste of the saccharin mist while the irritant fume QLFT elicits the test subject's involuntary response to the fume.) Appendix C of the asbestos standard, 29 CFR 1910.1001, should be used as a guide for performing fit testing.

It should be noted that some molded fabric type respirators are valveless or have an exhalation valve which cannot be blocked by the hand. An effective fit check may be difficult to perform on these respirators. In these cases, fit checks should be done according to manufacturer's instructions.

FACTOR #2: The filtration characteristics and filtration efficiencies of the different types of particulate respirators, e.g. Dust/Mist, Dust/Fume/Mist, and HEPA. Comparison and clarification about the significance of the size of the challenge particulate, the mean aerodynamic diameter of the challenge particulate, and whether the filtration efficiency is dependent on filter loading.

The OSHA standards on respiratory protection, 29 CFR 1910.134, and air contaminants, 29 CFR 1910.10XX, require the use of respirators which are jointly approved by the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11. The test methods for air-purifying respirators equipped with particulate filters are prescribed in 30 CFR Part 11, Schedule K, which includes performance tests for single use, dust/mist, fume and HEPA filters. A discussion of different filter testing methods appears under Factor #3.

NIOSH's dust filter certification test requires a challenge of a very high concentration (50 milligrams per cubic meter) of silica dust, and an integrated penetration is the only required measurement at the end of a 90 minute test. The integrated measurement method permits the use of less efficient filter media which allow the penetration of fine particles until a cake is built upon the respirator filter surface (filter "loading"). This in turn decreases the penetration of particles, and meets the integrated penetration requirement. This type of measurement also applies to the dust/mist/fume filter.

CDC[3] states that the size of the droplet nuclei carrying the TB bacilli is between 1-5 μm There is no assurance that the MSHA/NIOSH approved dust/mist or dust/mist/fume filters classified in accordance with the current certification methods would remove

[3] NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Atlanta, Georgia: U.S. Department of Health and Human Services, Public Health Service, 1992.

airborne droplet nuclei containing the TB bacteria. Furthermore, the certification tests for dust/mist and dust/mist/fume filters do not evaluate **initial** filter efficiency.

Respirators with HEPA filters are the only currently available certified respirators that meet or exceed the required filter efficacy against low-concentration aerosols in the size range of droplet nuclei. MSHA/NIOSH-approved HEPA filters are effective against all sizes of particles (including the 1 to 5 μm range) upon first donning (without dependence on filter loading). In addition, every HEPA filter must be verified by the manufacturer for meeting the di-2-ethylhexly phthalate (DOP) penetration requirement described below.

FACTOR #3: The NIOSH evaluation methods for the different types of particulate respirators.

The NIOSH evaluation method is detailed in Schedule K of 30 CFR Part 11. An overview of Schedule K is as follows:

Different test schedules are listed in 30 CFR Part 11 for approval of different classes of respirators. The test methods for air-purifying respirators equipped with particulate filters are prescribed in Schedule K of this part. It includes performance tests for single use, dust/mist, dust/mist/fume, and HEPA filters. Usually, a respirator which receives the high-efficiency approval also includes the fume, dust and mist approvals. The fume approval also includes the approval for dust and mist. The dust approval also includes the approval for mist.

Three types of aerosols, silica, lead fume, and di-2-ethylhexyl phthalate, have been used for certifying particulate respirators. Polydisperse silica dust having a projected particulate diameter of 0.4 to 0.6 micrometers (measured by a microscope) is used for testing dust and single use filters. The test is performed inside a dust chamber at a concentration between 50 and 60 milligrams per cubic meter. The temperature is approximately 25°C and the relative humidity may vary from 20 % to 80 %. The test period is 90 minutes at a flow of 32 liters per minute for non-powered respirators. The flow rate for tight and loose fitting inlet covering powered air-purifying respirators (PAPR) is 115 liters (4 cubic feet) per minute and 170 liters (6 cubic feet) per minute respectively, and the test period for the PAPR's is 4 hours. Since single use respirators are valveless, the filter performance test is performed on a breathing machine at a rate of 24 respirators per minute with a minute volume of 40 liters per minute.

When the filters are placed in pairs or in triplets, the air flow to each filter element will be reduced accordingly. For example, if two filter elements are used on a twin cartridge respirator, the air low to each filter will be half of 32 lpm or 16 lpm. The maximum allowable filter penetration is 1% for all filters listed in Subpart K, except for the HEPA filter which is 0.03%.

The performance test requirements for the polydisperse silica mist is similar to the test for silica dust, except that an aqueous suspension of silica at a concentration between 20 and

25 milligrams per cubic meter replaces the silica dust, and also the test time for the non-powered respirator is 312 minutes.

The polydisperse lead fume test is performed in a test chamber with freshly generated lead oxide fumes at a concentration from 15 to 20 milligrams of Pb per cubic meter of air. Other test conditions, including air flow, are the same as the silica dust test except that the test period is 312 minutes for non-powered, and 4 hours for powered respirators. The maximum allowable filter penetration is 1%. The aerodynamic sizes of silica dust and lead fume have been determined by NIOSH. The silica dust has a mass median aerodynamic diameter (MMAD) of 2 μm, and the lead fume has a MMAD of 1 μm.

The di-2-ethylhexly phthalate (DHEP or DOP) test is performed on the HEPA filter. The filter is challenged with a heat generated monodisperse oil mist of DHEP having a size of 0.3 micrometer at a concentration of 100 milligrams per cubic meter. The air flow is 32 and 85 liters per minute for a single filter, or 16 and 42.5 liters per minute when the filters are used in pairs. The maximum allowable penetration is 0.03% after a test period of 5 to 10 seconds. The HEPA filter cartridge is the only respirator component listed in 30 CFR Part 11 for which the DOP test is performed on each cartridge manufactured.

The DOP test is designed for certifying filters for protection against radioactive nuclei. In order to provide the maximum protection to the respirator wearer, the most penetrating particle size is used to challenge the filter. Particles having a size of 0.3 μm, with a monodisperse distribution, are the most difficult size for filters to remove. A thermally generated monodisperse oil mist would meet the size criterion for the most penetrating aerosol. A very tight initial penetration requirement of 0.03% has been set for certifying filters for protection against radionuclides. Filters that meet the penetration requirement are called “high-efficiency” filters.