

changes, the program is to be revised. In addition, paragraph (f)(2)(iv) requires that employers, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. This provision also requires that a copy of the program be submitted to the Assistant Secretary and/or the Director, if requested.

Paragraph (f)(3) sets out the respirator characteristics that must be satisfied in order to provide employees with a respirator that will protect them against aerosolized *M. tuberculosis*. These criteria are presented in performance-oriented language to provide flexibility in choice of respirators and have been drawn from CDC recommendations (Ex. 4B). CDC has based these criteria on currently available information relative to respirators that includes:

\* \* \* (a) data on the effectiveness of respiratory protection against noninfectious hazardous material in workplaces other than health-care settings and on an interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*; (b) data on the efficiency of respirator filters in filtering biological aerosols; (c) data on face-seal leakage; and (d) data on the characteristics of respirators that were used in conjunction with administrative and engineering controls in outbreak settings where transmission to HCWs and patients was terminated (Ex. 4B).

The CDC Guidelines go on to state:

Available data suggest that infectious droplet nuclei range in size from 1 [micron] to 5 [microns]; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particle in this range. Fifty liters per minute is a reasonable estimate of the highest airflow rate an HCW is likely to achieve during breathing, even while performing strenuous work activities (Ex. 4B).

In their 1994 TB guidelines, the CDC states:

Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following standard performance criteria:

1. The ability to filter particles 1  $\mu$ m in size in the unloaded state with a filter efficiency of  $\leq 95\%$  (i.e., filter leakage of  $\leq 5\%$ ), given flow rates of up to 50 L per minute.
2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of  $\leq 10\%$ .
3. The ability to fit different facial sizes and characteristics of HCWs [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 facepiece fit, in accordance with standards established by the Occupational Safety and Health Administration (OSHA) and good industrial hygiene practice, by HCWs each time they put on their respirators. (Ex. 4B)

The various respirator provisions that OSHA is proposing rely heavily on the CDC's aforementioned respirator performance criteria. The second, third, and fourth CDC criteria are addressed by paragraphs (f)(3)(i) (A) and (B) and paragraph (f)(5)(ii). Paragraph (f)(3)(i) requires the employer to select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators must be capable of being: (A) Qualitatively or quantitatively fit tested in a reliable way to verify a face-seal leakage of no more than 10%; and (B) fit checked by the employee each time the respirator is donned. Paragraph (f)(5)(ii) requires that employers assure that each employee who must wear a tight-fitting respirator is fit tested and passes the fit test. All of these provisions deal with the ability of the respirator to achieve a good face seal with a particular employee.

Good face fit is critical in assuring proper performance of respiratory protection. When an employee inhales through a respirator that does not fit properly, contaminated workplace air can enter the respirator through gaps and leaks in the seal between the face and the facepiece. OSHA is requiring the employer to provide each employee who must wear a respirator with one that fits. To do so, the employer will have to consider the facial sizes and characteristics in his or her workplace. It is not necessary for the employer to have respirators of different sizes of characteristics unless the employees need them. In other words, an employer may need only one or two styles and sizes. However, in workplaces where employees have different facial sizes and characteristics, obtaining proper respirator fit for each employee may require the fit testing of different mask sizes, possibly from several manufacturers. Proper respirator fit reduces inhalation leakage through the face-to-facepiece seal to a minimum.

Once a respirator has been selected based on its ability to achieve an adequate face-to-facepiece seal, the employee must be able to check that the respirator is properly seated and sealed to his or her face each time it is donned. The respirator, therefore, must be able to be fit checked by the employee. This is a procedure in which the employee covers the filter surface of the respirator and inhales (negative fit check) and exhales (positive fit check). If the respirator has an exhalation valve, this valve must be covered during the positive fit check. A respirator that is properly sealed will firmly adhere to the wearer's face upon inhalation due to the negative pressure created inside the mask. Upon exhalation, the mask

should lift slightly off of the wearer's face to allow air to escape around the face seal. Employers should be aware that a problem could exist with fit checking some disposable negative pressure respirators. That is, it is difficult to cover the entire filter surface, thereby hindering the employee's ability to perform a proper fit check. At least one respirator manufacturer has developed a "fit-check cup" that covers the filter surface of their disposable respirator, thereby permitting the user to more easily perform a fit check. Reusable elastomeric facepiece respirators utilize filter cartridges that can be covered for performing a fit check.

CDC's first criteria, regarding filter efficiency, is addressed under paragraph (f)(3)(ii) of the standard. This provision requires the employer to select a respirator that will function effectively in the conditions of the work setting. In addition to meeting the criteria in paragraph (f)(3)(i) above, the respirator shall be, at a minimum, either a High Efficiency Particulate Air (HEPA) respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11, or an N95 respirator certified by NIOSH under the provisions of 42 CFR part 84.

NIOSH and MSHA are the government agencies charged with testing and certifying respiratory protective devices. It has always been OSHA's policy that respiratory protection must be certified by these agencies before being deemed acceptable. Until recently, HEPA respirators were the only NIOSH certified negative pressure respirators that met the CDC's filter efficiency criteria. However, on July 10, 1995, NIOSH's original respirator certification procedures for air-purifying particulate respirators, 30 CFR part 11, were replaced by revised procedures, 42 CFR part 84 (Ex. 7-261). Under the new procedures, all nonpowered air-purifying particulate respirators are challenged with a 0.3 micron particle (the most penetrating size) at a flow rate of 85 liters per minute. At the conclusion of the test, those respirators that pass are placed into one of nine classes of filters (three levels of filter efficiency, with three categories of resistance to filter efficiency degradation). The three levels of filter efficiency are 99.97%, 99%, and 95%. The three categories of resistance to filter efficiency degradation are labeled N (not resistant to oil), R (resistant to

oil), and P (oil proof). Given these categories, a type N95 respirator would meet or exceed the filter efficiency performance criteria set forth in the CDC guidelines which state that a respirator appropriate for use in protecting against transmission of tuberculosis must be able to filter particles 1 micron in size in the unloaded state with a filter efficiency of  $\geq 95\%$ , given flow rates up to 50 liters per minute (Ex. 4B). The underlying reasoning for the acceptability of type N95 respirators is that their filter efficiency of 95% for a 0.3 micron particle will exceed 95% filtering efficiency for a particle three times as large (i.e., 1 micron). Also, the Agency assumes that oil aerosols are not likely to be found in the work settings covered by the standard, and therefore, that the use of a category N respirator would be sufficient. However, if oil aerosols are present, the employer would be expected to consider this when selecting the category of respirator to be used in his or her workplace.

OSHA is permitting the employer to select either a HEPA respirator certified under 30 CFR part 11 or a respirator certified under 42 CFR part 84, since particulate respirators certified under both of these regulations are currently on the market. HEPA respirators are the only nonpowered particulate respirators certified under 30 CFR part 11 that meet the CDC guidelines filtration criteria. However, applications for certification of nonpowered particulate respirators under 30 CFR part 11 are no longer being accepted by NIOSH. Therefore, dwindling stocks of HEPA respirators certified under that regulation will eventually lead to their unavailability, and employers will of necessity be selecting respirators from those approved under 42 CFR part 84.

Paragraph (f)(4)(i) states that the employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any conditions that prevent such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or facial hair that interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal. Paragraph (f)(4)(ii) requires the employer to assure that each employee who wears corrective glasses or goggles wears them in such a manner that they do not interfere with the seal of the facepiece to the face of the wearer. Tight-fitting facepiece respirators rely on a good face-to-facepiece seal in order to achieve effective protection. Therefore, the employer must not allow

employees to wear such respirators with conditions that prevent such a seal. Several studies support the prohibition of facial hair that comes between the sealing surface of the facepiece and the face (Exs. 7-243, 7-242, 7-182). A study by Skretvedt and Loschiavo found that bearded subjects wearing half-mask respirators had a median face seal leakage 246 times greater than clean shaven subjects. They go on to state:

Even though a number of bearded individuals did obtain fit factors above OSHA's minimum requirement for half-mask respirators, they all failed the qualitative fit test. No relationship was found between the length, shape, density and texture of beards and the amount of face seal leakage. Therefore, the only way to identify bearded negative-pressure respirator wearers obtaining fit factors above OSHA's minimum requirements would be by performing a quantitative fit test on them. However, even if quantitative fit tests are performed on all bearded individuals, another problem must be faced. The drop in the fit factor experienced when a beard is present is of such magnitude that no confidence can be placed in the protection the respirator will provide in the workplace or in future donnings. All respirator users experience variability from one donning to the next. This fit variability from donning to donning occurs due to changes in strap tension, positioning on the face, and a host of other variables. Donning-to-donning fit variability for bearded individuals will be even greater since additional variables will be introduced. A beard is a dynamically changing thing. The hair length constantly changes as well as the orientation of the hair in the sealing surface. Beards also accumulate moisture, natural oils, and debris from the workplace. Even though a percentage of bearded respirator wearers obtain fit factors slightly above OSHA's minimum requirements, the tremendous drop in fit factor resulting from the presence of a beard is such that the safety factor necessary to accommodate the variability of fit no longer exists. In summary, although bearded individuals may be able to achieve fit factors above OSHA's minimum requirements during a specific quantitative fit test, the drop in protection caused by a beard coupled with the large fit variability from donning to donning makes it quite likely that the individual will not obtain the minimum required protection in the workplace. (Ex. 7-243)

Therefore, while a bearded respirator wearer may be able to obtain a satisfactory fit on a particular occasion, one cannot assume that the individual can reliably be expected to achieve that same protection level each time the respirator is used. Beards grow and change daily. Each time a respirator is donned there is fit variability. Such variability in face seal is greatly increased for bearded workers. This large variability in fit means that a reliable seal cannot be reasonably expected. This provision should not be

construed as a blanket prohibition on beards among respirator wearers. There are other types of respiratory equipment such as hoods, helmets and suits that can be worn by employees with beards, since they do not rely upon a tight facepiece fit. In addition, this provision refers to facial hair that interferes with the facepiece seal rather than simply growth of beard or sideburns. It is the interference with the facepiece seal that is the concern, not the presence of facial hair. Other conditions such as the absence of normally worn dentures, facial scarring and cosmetic surgery change the geometry of the face, thereby changing the ability of the respirator wearer to achieve a facepiece seal. Facepiece seal may also be compromised when headgear, temple pieces and nose pieces of glasses, the edges of goggles and so forth project underneath the respirator's sealing surface. Both of the above provisions are intended to eliminate or minimize conditions that jeopardize face-to-facepiece seal and could permit leakage of outside air into the facepiece.

Paragraph (f)(4)(iii) states that disposable respirators must be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use. It is not expected that the filter media of respiratory protective devices would become occluded with particulates in the work settings covered by this standard. However, if excessive resistance is noted, the respirator must be discarded. Also, such respirators must be structurally sound in order to provide a proper face seal and maintain their effectiveness. Whenever physical damage occurs (e.g., the respirator is crumpled or torn; the flexible face seal is damaged; a head strap is broken), effective functioning cannot be assured and the respirator must be replaced. In addition, other conditions may render the respirator unsuitable for use (e.g., the respirator may become contaminated with blood), thereby requiring discard.

In view of the types of activities carried out and the environmental conditions encountered in the work settings covered by this standard, OSHA is proposing to allow the multiple use of disposable respirators. However, this action should in no way be construed as setting a precedent for the use of disposable respirators in any other OSHA standards or in how OSHA views multiple use of disposable respirators in other work settings. OSHA requests comment on the approach taken in this proposal toward the reuse of disposable respirators.

Paragraph (f)(4)(iv) requires the employer to assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. In performing the fit check, the procedures in Appendix B or other procedures recommended by the respirator manufacturer that provide equivalent protection to the procedures in Appendix B must be used. This provision is supported by a recent study by Meyers et al. that concluded:

\* \* \* for wearers of respirators that have been properly fit by a recognized fit test, conducting fit checks according to the manufacturer's instructions can be a useful tool for more consistently maintaining the quality of respirator donning. (Ex. 7-233)

The use of such seal checks are a way of helping to assure that attention is paid to obtaining an adequate facepiece seal each time a respirator is used.

The standard requires, under paragraph (f)(4)(v), that respirators be immediately repaired, or discarded and replaced when they are no longer in proper working condition. Examples of these changes in condition would be that a strap has broken, the respirator has lost its shape, or the face seal can no longer be maintained. As discussed above, respirators must be in good working condition in order to function effectively. Therefore, it is imperative that they not be used if they have been impaired in any way. The respirator manufacturers can supply replacement parts for damaged portions of their elastomeric respirators. Disposable respirators cannot be repaired and must be discarded when damaged.

Paragraph (f)(4)(vi) stipulates that the employer shall permit each employee to leave the respirator use area as soon as practical to: (A) change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or (B) wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use. This provision encourages and facilitates the proper use of respirators by employees by authorizing employees to take specific actions to assure the effective functioning of their respirators. This provision is consistent with requirements in other health standards (e.g., Lead, 29 CFR 1910.1025; Cadmium, 29 CFR 1910.1027).

Considering the health problems that may be exacerbated with respirator use and their associated detrimental effects on an employee, the proposal states in paragraph (f)(4)(vii) that each employee

required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section to determine whether any health conditions exist that could affect the employee's ability to wear a respirator. In addition, paragraph (f)(4)(viii) states that no employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to continue to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be in accordance with paragraph (g)(5)(iii) under Medical Removal Protection of this section.

Common health problems that could interfere with respirator use include claustrophobia (an intolerance of feeling enclosed and a subjective feeling of breathing difficulty), chronic rhinitis, nasal allergies that would necessitate frequent removal of the respirator to deal with nasal discharges, and chronic sinusitis. In addition, difficulties with the use of respirators may arise in employees with respiratory or cardiac diseases. Respiratory diseases include chronic obstructive pulmonary disease, emphysema, asthma, and moderate to severe pneumoconiosis. Cardiac or cardiorespiratory diseases that may affect respirator wear include any type of congestive heart disease, other ischemic heart diseases, and hypertension.

As discussed further under paragraph (g)(5)(iv), Medical Surveillance, of this section, employees who are removed from work due to the inability to wear a respirator are afforded certain medical removal protection relative to retention of earnings, seniority, rights and benefits. The Agency believes that these provisions will encourage all employees, including those experiencing difficulty with respirator use, to participate in the Medical Surveillance Program and will minimize an employee's fear of losing his or her job due to the possible inability to wear a respirator.

Paragraph (f)(5)(i) requires the employer to perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in Appendix B of this section.

Quantitative fit testing is an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the facepiece. One method of accomplishing this assessment utilizes a procedure whereby the level of penetration of a test agent of a known concentration is measured inside the facepiece of the respirator. In this quantitative fit test procedure, the respirator is worn in a stable test atmosphere containing a suitable challenge agent. The adequacy of fit is determined by measuring the actual levels of the challenge agent, both outside and inside the facepiece of the respirator. This provides a quantitative assessment of the fit (the fit factor). Fit testing allows the employer to continue testing different facepieces until a properly fitting respirator is identified and selected for the employee. Quantitative fit testing requires the use of moderately sophisticated testing equipment and is more expensive to perform than qualitative fit testing, which may reduce its availability in some work sites. Also, testing services may not be available in all parts of the country to provide quantitative fit testing services for small businesses.

Qualitative fit testing does not provide a numerical measure of the quality of the fit but simply determines whether a respirator fits or not. The outcome of the test is simply a pass or fail result. Qualitative fit testing involves the detection of a gas, vapor, or aerosol challenge agent through subjective means such as odor, taste, or nasal irritation. If the challenge agent's presence is detected, the respirator fit is considered to be inadequate. Qualitative fit testing is more subjective than quantitative testing because it depends on the individual's ability to detect the test agent.

OSHA believes that while quantitative fit testing has some advantages, qualitative fit testing conducted in accordance with the protocols described in Appendix B of this section can generally accomplish the intent of the standard, which is to assure that each employee is assigned and wears a respirator that provides a proper fit.

Paragraph (f)(5)(ii) states that the employer shall assure that each employee who must wear tight-fitting respirator passes a fit test: (A) at the time of initial fitting; (B) whenever changes occur in the employee's facial characteristics that affect the fit of the respirator; (C) whenever a different size or make of respirator is used; and (D) at least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, indicates that the annual

fit test of the employee is not necessary. This frequency of fit testing is necessary to assure that factors that may affect the proper fit of a respirator are detected and necessary adjustments are performed to assure the integrity of the face seal. For example, the fit of respirators is not standardized among manufacturers. Fit testing would be required, therefore, whenever a different size or make of respirator is used. In addition, a change in an employee's facial structure can compromise a respirator's face seal. Examples of such changes include loss of weight, cosmetic surgery, facial scarring, and the installation of dentures or the absence of dentures that are normally worn by the individual. Therefore, fit testing is required when any facial changes, such as those mentioned above, occur.

Requiring annual fit testing, unless the annual determination by the physician or other licensed health care professional indicates that the annual fit test is not necessary, assures that factors that could affect respirator fit are detected and the employee's respirator is adjusted or replaced as necessary. It is OSHA's intent in this provision that each employee be evaluated annually for respirator fit. This can be accomplished through either an actual fit test or through a person-to-person evaluation consisting of a questionnaire and personal observation by the evaluator carried out under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section. It should be noted that an annual determination of respirator fit is required, either through fit testing or the person-to-person evaluation. The employer may use the determination of the need for the annual fit test in lieu of an annual fit test if that determination indicates that a fit test is not necessary.

One of the criteria that must be satisfied when selecting respirators is a face seal leakage of 10% or less. OSHA considers any respirator that passes a qualitative fit test to meet this criteria. However, quantitative fit testing necessitates that a particular numerical value be achieved. Therefore, paragraph (f)(5)(iii) requires that when quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber. This value corresponds to a face seal leakage of 10% or less.

In order to assure that continuing protection is achieved by reusable and powered air purifying respiratory protective devices, it is necessary to establish and implement proper maintenance and care procedures. A lax attitude toward this part of the

respiratory protection program will negate successful selection and fit because the devices will not deliver the assumed protection unless they are kept in proper working order. A basic program for assuring proper respirator function would contain procedures for cleaning, inspection, repair, and replacement of respirators used in the workplace.

Paragraph (f)(6)(i) requires that the employer clean and disinfect the respirators using the manufacturer's recommended procedures at the following intervals: (A) as necessary for respirators issued for the exclusive use of an employee; and (B) after each use for respirators issued to more than one employee. Respirators that are not cleaned and disinfected can cause skin irritation and dermatitis. When more than one employee uses the same respirator, cleaning and disinfecting after each use provides the additional benefit of minimizing the respirator's role as a vehicle for spreading infections (e.g., skin, respiratory) between employees.

In order to assure continued respirator reliability, they must be inspected on a regular basis. Therefore, paragraph (f)(6)(ii) requires that respirators be inspected before each use and during cleaning after each use. As stipulated in paragraph (f)(6)(iii), such inspections must include: (A) a check of respirator function, tightness of connections and condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and (B) a check of the rubber or elastomer parts for pliability and signs of deterioration. In this way, the employer can assure that the respirator is functioning as intended, is able to be adjusted by the user, will not allow leakage through cracks or breaks in the respirator, and is pliable enough to achieve a proper face seal.

The standard also contains provisions regarding those respirators that are found to be deficient upon inspection. Paragraph (f)(6)(iv) states that respirators that fail to pass inspection must be removed from service and repaired or adjusted in accordance with the following: (A) repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer and by persons appropriately trained to perform such operations; (B) only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and (C) reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for

adjustment or repair. It is self-evident that repairs to respirators should only be performed by trained individuals, using parts designed for the specific respirator under repair (not all respirator designs are identical), and that the individual should not attempt repairs that he or she is not qualified to undertake or which are not recommended by the manufacturer.

Another important aspect of assuring appropriate respirator function is proper storage. Therefore, paragraph (f)(6)(v) stipulates that the employer assure that respirators are stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, damaging chemicals and that prevents deformation of the facepiece or exhalation valve. Proper storage, of both new respirators and those already in service, assists in maintaining appropriate respirator function by minimizing conditions that may cause deterioration of the respirator or filter, interfere with filter efficiency, change face seal geometry, and prevent sealing of valves against inhalation of contaminated air.

As discussed previously, OSHA accepts those respirators certified by MSHA and NIOSH. Therefore, paragraph (f)(7)(i) requires that filters, cartridges, and canisters used in the workplace are properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service. The employer must assure that the existing NIOSH approval label on a filter, cartridge, or canister is not intentionally removed, obscured, or defaced while it is in service in the workplace, as required by paragraph (f)(7)(ii) of this section.

Paragraph (f)(8) requires the employer to review the overall respiratory protection program at least annually, and conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The reason an employer must conduct an annual review and inspections as necessary is because respirators are utilized as supplemental and, in some instances, sole protection to prevent transmission of infectious TB. Therefore, it is of primary importance to assure proper implementation of the program. The review of the program must include an assessment of each element required under paragraph (f)(2) of this section. Once the respiratory protection program is implemented, the employer retains responsibility for detecting and

addressing problems that arise. While the written respiratory protection program is required to be reviewed and updated under paragraph (f)(2)(iii) of the standard, the overall review requires that the employer evaluate actual implementation in the workplace. Consequently, this provision stipulates inspections of the workplace and an assessment of each element required under paragraph (f)(2) of this section to assure proper implementation of the program.

OSHA believes that the proposed provisions regarding respirators are both appropriate and justified. OSHA seeks comments and data on all aspects of the proposed respirator requirements.

#### *Paragraph (g) Medical Surveillance*

##### (1) General

The purpose of this section is early detection and prevention of disease through employee medical histories and physical examinations, TB skin testing, medical management and follow-up of exposure incidents and skin test conversions, and medical removal of employees with suspected or confirmed infectious TB. These requirements are designed to ensure early detection of TB infections and disease by providing appropriate medical examinations to enable identification of infection or disease and to minimize the spread of TB to other employees in the workplace. Additionally, there are requirements in this section to assure that employees required to wear respiratory protection are evaluated to determine their ability to wear a respirator and advised about the need for annual fit testing. The needs of employees who have health conditions that might require special attention are also addressed (e.g., allergy testing, more frequent screening, or further medical examinations to diagnose TB).

Paragraph (g)(1) calls for medical surveillance to be provided for each employee who has occupational exposure, as defined in this standard. Occupational exposure may result in TB infection and the subsequent development of TB disease. Paragraphs (c)(1)(i, ii), (exposure determination) require the employer to identify employees with occupational exposure in the facility. These employees must be offered medical surveillance.

OSHA believes that early detection and management of exposed employees helps prevent severe illness and death. According to CDC's 1994 edition of the Core Curriculum on Tuberculosis (Ex. 7-93), approximately ten percent of the persons infected will develop active TB disease at some point in their lives (Exs.

4B, 7-50, 7-93). Five per cent of those infected develop disease within the first two years following infection and another five percent develop disease later in their lives. Immunosuppressed persons are at a considerably greater risk of developing active disease following a TB infection. For example, individuals infected with HIV and TB have been estimated to have a 8-10% risk per year of developing active disease (Ex. 7-50). However, according to the American Thoracic Society:

Clinical trials have shown that daily isoniazid preventive therapy for 12 months will reduce the risk of developing tuberculosis in infected persons by about 70 percent and in over 90 percent of patients who are compliant in taking the medications. (Ex. 5-80)

Most infected people have a positive reaction to the TB skin test within 2-10 weeks after exposure. Consequently, early detection of newly infected workers is critical as it permits early initiation of appropriate therapy and results in a decrease in morbidity and mortality.

Paragraph (g)(1)(ii) requires that information about the signs and symptoms of pulmonary tuberculosis disease, a medical history, a physical examination, TB skin testing, medical management and follow-up, and if indicated, other related tests and procedures and medical removal protection if the employee develops infectious TB, be provided to each employee in work settings described in paragraph (a) *Scope* who sustains an "exposure incident." This provision is applicable when the employee has not been categorized as having occupational exposure in the employer's Exposure Control Plan. OSHA recognizes that there may be times when employees who are not "reasonably anticipated" to have occupational exposure to TB may be exposed, (e.g., if engineering controls break down or an individual with infectious tuberculosis is unidentified during intake procedures). Employees exposed under such circumstances incur the risk of TB infection and subsequent disease (Ex. 7-93) as a result of their work duties. OSHA includes this provision so that these employees are provided protection.

Paragraph (g)(1)(iii)(A) requires the employer to provide all medical surveillance at no cost to the employee. This is consistent with OSHA policy. Providing services at no cost to the employee is an important factor in successful workplace health and safety programs because it encourages employee participation in medical surveillance programs.

Paragraph (g)(1)(iii)(B) requires that all medical surveillance be provided at a reasonable time and place for the employee. Convenience of these procedures increases the likelihood of employee participation in the program. This helps assure that employees receive the full benefits provided by the standard. OSHA recognizes the need for this provision and has included it in other standards (e.g., Ethylene Oxide, 29 CFR 1910.1047; Asbestos, 29 CFR 1910.1001; and Bloodborne Pathogens 29 CFR 1910.1030).

Paragraph (g)(1)(iii)(C) states that all medical surveillance is required to be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA has included in paragraph (j)

*Definitions*, a description of the licensed health care professional. Such an individual is a physician or other health care professional who holds a license enabling her or him to independently provide or be delegated the responsibilities to provide some or all of the health care services required by this paragraph. In several states, nurse practitioners may be licensed to independently perform or supervise the evaluations and procedures required by this paragraph. In such cases, the requirements of this standard can be accomplished by those practitioners. In addition, where registered nurses are licensed to perform or supervise some of the requirements of this standard, those requirements can be accomplished by those professionals.

Paragraph (g)(1)(iii)(D) requires that medical surveillance procedures be provided according to recommendations of the CDC, current at the time these procedures are performed, except as specified by this paragraph (g). In other words, employers must comply with paragraph (g), and with the most current CDC recommendations in providing medical surveillance. OSHA has set forth what an employer must do to prevent or minimize occupational exposure in the employer's workplace. However, CDC, an agency of the U.S. Public Health Service (USPHS), follows the epidemiology of *M. tuberculosis* and periodically revises and updates its guidelines and recommendations to reflect changes in the diagnosis and treatment of TB. OSHA believes that in addition to meeting the requirements of paragraph (g), it is appropriate to follow CDC recommendations, which address screening, medical evaluations, TB skin test procedures and follow-up (e.g., the administration and interpretation of skin tests).

OSHA recognizes the dynamic nature of medical knowledge relating to

tuberculosis and notes that CDC recommendations current at the time of the standard's publication may differ from recommendations at some future time when an employee evaluation takes place. Knowledge about tuberculosis is expanding. For example, the medical response to HIV/AIDS as related to tuberculosis continues to evolve. These are the reasons why OSHA has not simply required the employer to comply with a particular CDC guideline. OSHA believes that incorporating the CDC recommendations into the standard by reference enhances the quality of medical surveillance. This assures that employees are provided the most current and effective evaluation and treatment. Furthermore, the CDC recommendations provide consistency with regularly updated medical science and health care practice. A similar provision was included in the Bloodborne Pathogens standard 29 CFR 1910.1030 and met with widespread acceptance from the regulated community. The CDC recommendations cover the specific details of the medical protocols.

Paragraph (g)(1)(iv) requires that all laboratory tests be performed by an accredited laboratory. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. (For an explanation of "accredited laboratory" see paragraph (j) *Definitions* below). This accreditation process is required to assure a measure of quality control so that employees receive accurate information concerning their laboratory tests. The accreditation requirement assures long-term stability and consistency among laboratory test procedures and interpretations of results. OSHA recognizes the need for this requirement and has included it in other standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

## (2) Explanation of Terms

This paragraph explains the terms used in paragraph (g) *Medical Surveillance*. Paragraphs (g)(2)(i) to (g)(2)(vii) include explanations of the "medical history", the "physical examination (with emphasis on the pulmonary system, signs and symptoms of infectious tuberculosis, and factors affecting immunocompetence)", "TB skin testing", the "face-to-face determination of ability to wear a respirator and need to be re-fit tested", "medical management and follow-up", "other related procedures or tests determined to be necessary", and "Medical Removal Protection". The

applications section, paragraph (g)(3), describes what must be provided and at what time.

Paragraph (g)(2)(i) describes a medical history, during which the examiner questions the employee in order to gather information on the employee's pulmonary system, TB exposure, vaccination, testing and disease status and factors affecting immunocompetence. A medical history questionnaire may be used as a starting point for this discussion. OSHA believes that a medical history is essential for interpreting the TB skin test results, which are also required by this paragraph (g). The CDC Core Curriculum states:

TB skin testing is a useful tool, but is not perfect. Several factors can affect the skin test reaction: for example, infection with mycobacteria other than *M. tuberculosis* and vaccination with BCG. These factors can lead to false-positive reactions \* \* \* Other factors, such as anergy, can lead to false-negative reactions. (Ex. 7-93).

Therefore, the medical history is used to assist in interpreting the TB skin test results. The medical history also provides information regarding the employee's potential for increased risk if exposed to tuberculosis. Based on this information, discussions between the employee and the examiner regarding the employee's increased risk can assist the employee in decision-making.

Paragraph (g)(2)(ii) describes the physical examination. The physical examination is to emphasize the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence. Such an examination assists the examiner in detecting evidence of active disease (e.g., rales), differentiating TB disease from other causes of cough or other signs/symptoms associated with TB disease, and ascertaining whether signs are present that are compatible with an immunocompromising health condition. The physical examination is also required when an employee has signs or symptoms of TB or after a TB skin test conversion and at other times, if indicated.

That the pulmonary system is emphasized in both the medical history and physical examination assures that the employee is evaluated with specific attention to the most common site of infectious TB. Although extrapulmonary tuberculosis can occur (e.g., in bone, meninges of the brain, and draining abscesses), it is not usually a source of infection for others. The language "with emphasis on the pulmonary system" is used to indicate that while the history and physical examinations evaluate the health of the patient as a whole,

particular emphasis should be placed on the pulmonary system.

Paragraph (g)(2)(iii) explains the required TB skin testing. TB skin testing is the cornerstone for early detection of TB transmission among exposed workers. The American Thoracic Society notes that:

Although currently available TB skin tests are substantially less than 100% sensitive and specific for detection of infection with *M. tuberculosis*, no better diagnostic methods have yet been devised. (Ex. 5-4)

The TB skin test is an important tool that is useful in identifying employees who may be eligible for appropriate, early treatment; initiating contact investigations; and evaluating the effectiveness of the facility's control program. The requirement for TB skin testing is supported by AHA (Exs. 7-61, 7-29), APIC (Ex. 7-30), AIHA (Ex. 7-170) and the CDC 1994 Core Curriculum which states, "TB screening should be done in groups for which rates of TB are substantially higher than the general population." [Ex. 7-93]. In this document, CDC specifically mentions screening for health care workers, staff of long term care facilities, correctional facilities, hospices, drug treatment centers, and nursing homes.

Paragraph (g)(2)(iii) describes the requirement for TB skin testing. TB skin testing, which only applies to employees whose TB skin test status is not known to be positive, includes anergy testing if indicated, and consists of an initial 2-step protocol for each employee who has not been previously skin tested and/or for whom a negative test in the past 12 months cannot be documented. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be used to fulfill the skin testing portion of the initial medical surveillance requirements. For example, if an employer has a new or existing employee for whom: (1) a TB skin test has not previously been performed, or (2) a negative skin test result within the past 12 months that cannot be documented, the employer is required to provide an initial two-step skin test for the employee. Conversely, if the employer can document a negative skin test result from a test performed on the employee within the past 12 months, that test can be used to fulfill the initial skin testing requirement of this section. Subsequent periodic retesting of the employee is to be performed in accordance with paragraph (g)(3), as discussed below.

It is important for the employer to determine the current TB skin test status

of employees prior to their initial assignment to a job with occupational exposure. This "baseline" status can then be used to evaluate changes in the employees' TB skin test.

In their 1992 guidelines, the American Thoracic Society recommended the following:

Individuals at high risk for TB should have a TB skin test at least once to assess their need for preventive therapy and to alert the health care providers of those with positive skin tests of this medical problem. In institutional settings, baseline information on the TB skin test status of staff and residents is a means of identifying candidates for preventive therapy as well as determining whether transmission of TB is occurring in the facility. For this reason, TB skin testing upon employment or upon entry should be mandatory for staff and residents \* \* \* (Ex. 5-80)

Previous BCG vaccination is not a contraindication for skin testing. In its 1994 guidelines, the CDC states:

During the pre-employment physical or when applying for hospital privileges, HCWs who have the potential for exposure to *M. tuberculosis* [sic], including those with a history of BCG vaccination, should have baseline PPD skin testing performed \* \* \*

BCG vaccination may produce a PPD reaction that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*. For a person who was vaccinated with BCG, the probability that a PPD test reaction results from infection with *M. tuberculosis* increases (a) as the size of the reaction increases, (b) when the person is a contact of a person with TB, (c) when the person's country of origin has a high prevalence of TB, and (d) as the length of time between vaccination and PPD testing increases. For example, a PPD test reaction of  $\geq 10$  mm probably can be attributed to *M. tuberculosis* in an adult who was vaccinated with BCG as a child and who is from a country with a high prevalence of TB. (Ex. 4B)

CDC does not state that BCG vaccination negates the need for baseline and periodic skin testing but does state that skin tests on vaccinated individuals need to be interpreted carefully. OSHA's proposed rule is consistent with the CDC Guidelines on this point. PPD testing is thus not contraindicated for BCG vaccinated employees; however, such prior vaccination does mean that other factors, such as the age of the employee and the extent of induration, must be considered in interpreting the results.

The purpose of performing a *two-step test* is to correctly identify the baseline TB skin test status of those employees who are infected with TB but whose sensitivity to the tuberculin testing material may have waned over the years. This procedure enhances the proper interpretation of subsequent

positive TB skin test results and is based upon current CDC and American Thoracic Society recommendations (Exs. 5-80, 6-15, 7-52, 7-93, 7-169).

*Two-step testing* requires an employee to be tested initially and, if the test results are negative, to be tested again within 1-3 weeks. This second test stimulates or "boosts" the body's response to the testing material and results in a more valid reaction. For example, an employee who has not been recently tested but who is infected with TB from an earlier exposure may fail to respond to this current test because his or her immune response has waned over time. However, a second test of this employee will produce a positive TB skin test that more accurately reflects his or her true TB skin test status. Thus, the initial use of a two-step testing procedure ensures that the baseline TB skin test is an accurate reflection of the employee's TB status and will reduce the likelihood of misinterpreting a "boosted" reaction on subsequent tests as a conversion. Two-step testing is also appropriate for individuals who have been BCG vaccinated, since these individuals can exhibit a boosted reaction. Therefore, two-step testing of BCG vaccinated individuals can be used to determine their baseline status, although the skin test results must be interpreted in light of their previous BCG vaccination.

The two-step testing procedure does not identify those persons who are truly anergic and, therefore, are not capable of mounting a typical immune response to the test material. Evaluation of adequate immune response, when determined to be necessary by the physician or other licensed health care professional, as appropriate, is determined through anergy testing, and this is provided for in the explanation of TB skin testing in paragraph (g)(2)(iii).

The CDC recommendations are the guiding documents for TB skin test protocols. By referring the employer to these recommendations in Paragraph (g)(1)(iii)(D), OSHA allows for future changes in protocols and procedures that result from continuing research. Consistent with the CDC guidelines (Exs. 3-33, 3-35, 3-32, 6-15), the American Thoracic Society recommends:

The Mantoux test with 5 Tuberculin Units (TU) of PPD may be used as a diagnostic aid to detect tuberculous infection and to determine the prevalence of infection in groups of people. (Ex. 5-4)

Proper administration of a TB skin test results in a reaction described as a classic example of a delayed (cellular) hypersensitivity reaction. This reaction

indicates infection with mycobacterium, most commonly *M. tuberculosis*. The reaction characteristically begins in 5-6 hours, is maximal at 48-72 hours, and subsides over a period of days (Ex. 5-4).

Proper administration and interpretation of the test is critical and can be complex. In 1990, the American Thoracic Society revised the criteria for interpreting the TB skin test (Ex. 5-4). Information such as the health status of the tested employee, history of BCG vaccination, recent close contact with persons with active TB, chest x-ray results, and other factors must be considered when interpreting the TB skin test results. CDC has established criteria for a TB skin test *conversion*; that is, when an employee's TB skin test results change from negative to positive, indicating a recent TB infection (Ex. 4-B).

Because of the complexity in properly administering and interpreting TB skin tests, it is essential that only trained individuals perform this function. For this reason, TB skin testing is to be administered and interpreted by or under the supervision of a physician or other licensed health care professional as appropriate and according to CDC recommendations. This language allows employers to choose from a variety of health care professionals who can administer and interpret TB skin tests. OSHA is aware that in some worksites, employees have been allowed to read and interpret their own skin test results. A surveillance system that allows self-reading and interpretation of TB skin tests can be problematic. With regard to interpretation of TB skin test results, the American Thoracic Society states:

Intelligent interpretation of skin test results requires a knowledge of the antigen used (tuberculin), the immunologic basis for the reaction to the antigen, the technique(s) of administering and reading the test, and the results of epidemiologic and clinical experience with the test. (Ex. 5-4)

In its 1994 *Core Curriculum on Tuberculosis* (Ex. 7-93), CDC describes the complexities of interpreting the induration resulting from TB skin testing. A number of factors can affect the size of a TB skin test induration relative to whether or not the test should be interpreted as being positive. For example, induration of 5 mm or more is classified as positive for persons with known or suspected HIV infection, while an induration must be 10 mm to be classified as positive in persons who are foreign-born in high prevalence countries. An induration of 15 mm or more is classified as positive in certain other situations. In addition, TB skin

testing can result in both false positive and false negative results.

Clearly, interpreting TB skin test results requires professional expertise and must be performed by or under the supervision of a physician or other licensed health care professional, as appropriate, by an individual with training and experience in performing the test and interpreting the result. Proper use of the TB skin test as a medical surveillance tool will require two visits to the health care professional: one to receive the test and one to read/interpret the test results. However, considering the critical importance of this element, OSHA believes that allowing employees to read and interpret their own tests or allowing their peers to do so (unless they meet the criteria discussed above) compromises the quality and accuracy of the testing procedure.

Paragraph (g)(2)(iv) describes the determination of each employee's ability to wear a respirator and of his or her need for re-fit testing for employees required to wear a respirator. This face-to-face determination includes a verbal exchange between the employee and the examiner regarding the employee's health factors such as illness or injuries, that may impact his or her ability to wear a respirator (e.g. vascular or heart disease, asthma, claustrophobia, facial structure defects, certain skin conditions, etc.) (Ex. 7-64). Based on this history and the observation of the employee, the need for further testing or physical examinations for the ability to wear a respirator can be determined. In addition, assessment of the need for re-fit testing is to be performed, which assures that the examiner consider whether re-fit testing is needed. OSHA has included a note stating that the determination of the need for re-fit testing may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, as, for example, when a different size or make of respirator is used.

Paragraph (g)(2)(v) explains that medical management and follow-up include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease. The employer must provide medical management and follow-up for occupationally exposed employees with skin test conversions [paragraph (g)(3)(i)(D)], or those who undergo an exposure incident whether or not they are categorized as occupationally exposed [paragraphs (g)(1)(ii) and (g)(3)(i)(C)]. In addition, any time an occupationally exposed employee develops signs and symptoms of

infectious tuberculosis, medical management and follow-up are required [paragraph (g)(3)(i)(B)]. John E. McGowan addressed follow-up in the 1995 article entitled "Nosocomial Tuberculosis: New Progress in Control and Prevention," published in *Clinical Infectious Diseases*. He states,

If the PPD skin testing program for health care workers is to be useful, several steps are crucial. \* \* \* The institution also must make sure that the occupational health service undertakes careful follow-up of workers found to have positive TB skin tests or tuberculosis disease. This follow-up should include counseling, careful monitoring of therapy (when prescribed) until its completion and evaluation of fitness to return to work. (Ex. 7-248).

Paragraph (g)(2)(vi) explains that other related tests and procedures are any TB-related tests and procedures determined to be necessary by the physician or other licensed health care professional, as appropriate. These procedures or tests could include chest radiographs, sputum smears, or other testing determined to be necessary to make an assessment, a diagnosis, or medically manage the employee. An example of a program that integrates testing and examinations was given at the 1994 meeting of the Society for Occupational and Environmental Health, by Carol Murdzak who presented the University of Manitoba's Medical Surveillance program. Her presentation, entitled "Conducting a Medical Surveillance Program to Prevent and Control Transmission of TB in a Health Care Institution" demonstrates the use of skin testing and general review of health status for employee surveillance. Results of TB skin testing and the review of health status determine the need for chest x-ray and further medical evaluation in this program (Ex. 7-169).

### (3) Application

Medical examinations in the form of medical histories, physical examinations, TB skin testing and other related tests and procedures are necessary in order to promptly identify and treat employees with infectious tuberculosis.

Paragraph (g)(3), Application, specifies what an employer must provide. In each situation set forth in paragraph (g)(3), the employer must provide medical examinations, tests and procedures as specified. Some of the provisions are offered only "if indicated," which means that the physician or other licensed health care professional, as appropriate, has determined that further tests or procedures are needed. For example, an

employee who has no history of illness or being immunocompromised and whose TB skin test is negative at the time of initial assignment is not required to be offered a physical examination unless the examiner determines that a physical examination is indicated. However, if at the time of annual skin test, the employee has a skin test conversion, a physical examination is required.

Paragraph (g)(3)(i)(A) requires that, before the time an employee is initially assigned to a job with occupational exposure (or within 60 days from the effective date of the standard for employees already assigned to jobs with occupational exposure), the employee be provided with a medical history, TB skin testing, and, if indicated, a physical examination and other related tests and procedures.

OSHA requires the initial medical history to assist in assessing the employee's health. This information will provide a baseline health status that can be used to evaluate (1) whether the employee has a pre-existing condition that may be exacerbated by occupational exposure to TB and (2) any future health conditions that may arise that are relevant to occupational exposure to TB.

OSHA does not believe that an initial physical examination for all occupationally exposed employees is necessarily warranted. However, the Agency does believe that a physical examination, if determined to be indicated by the examiner based on the medical history and TB skin test results, is useful and effective.

The note to paragraph (g)(3)(i)(A) specifies that if an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has documentation of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The Agency realizes that employees may have received at least some of the elements of the required medical surveillance provisions shortly before the effective date of the standard. In these situations, a full TB examination would not need to be repeated.

In addition, the proposed standard allows the baseline TB skin testing status of an employee to be established by documentation of a TB skin test that was administered within the previous 12 months. For example, if an employee has a written record of a TB skin test within the last 12 months, that information can be used to document the employee's baseline TB skin test status and another TB skin test at the

time of the initial medical examination is not necessary. When utilizing results from a previous medical examination and skin test to fulfill the initial medical surveillance requirements, the employer must use the date(s) of the previous medical exam and skin test to determine the date(s) of the employee's next medical examination and skin test. In no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months. These provisions are designed to avoid unnecessary testing of employees and do not compromise the quality of the medical surveillance.

Information (e.g., medical history) obtained from a medical examination in the past 12 months is unlikely to change within this span of time. However, this may not be the case with regard to previous skin testing results. While OSHA is proposing to accept a skin test performed within the past 12 months as a substitute for performing an initial baseline skin test, an employer utilizing a new employee's negative skin testing result obtained more than 3 months prior to beginning the new job may be uncertain as to the source and time of infection if the employee tests positive at his or her next skin test. More specifically, conversion normally occurs within 3 months of infection. Therefore, an employee would have been negative at his or her last skin test, e.g., 7 months previously, and have been infected just after the skin test and subsequently converted. In such a case, an employer may rely on the previous negative skin test as the baseline does not need to test the new employee until 5 months later (i.e., annual skin test frequency), at which time the employee would test positive and be identified as a converter. In this situation, the new employer would not be able to determine if the employee's conversion had occurred as a result of exposure occurring previous to hire or from exposure in his or her current work setting. Regardless of the source of the conversions, the employer would be required by the standard to initiate medical management and a follow-up investigation, which might also entail skin testing other employees in the worksite to determine if other conversions had taken place, a step that would not be necessary if the employee had been correctly identified as positive upon entry into the workplace. In view of this, employers may choose to perform an initial baseline skin test on each new employee before the employee enters the work setting.

Once an employee is on the job, paragraph (g)(3)(i)(A) requires employers to periodically retest employees who have negative TB skin

tests in order to identify those employees whose skin test status changes, indicating that they have been infected. Because the baseline TB skin test provides only a "snapshot" of the TB skin test status of the employee and because exposure and subsequent infection can occur at any time, periodic testing is necessary. The American Thoracic Society recommends:

\* \* \* follow-up skin-testing should be conducted on at least an annual basis among the staffs of TB clinics, health care facilities caring for patients with HIV infection, mycobacteriology laboratories, shelters for the homeless, nursing homes, substance-abuse treatment centers, dialysis units, and correctional institutions. (Ex. 5-80)

When TB exposure results in infection, early identification allows employees to have options regarding prophylactic treatment, thereby reducing the likelihood that the infection will progress to disease.

OSHA recognizes the importance of periodic testing to monitor the status of employee's skin test results. In their 1994 Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, the CDC recommends that the frequency of PPD skin testing of employees be based upon the individual facility's risk assessment in conjunction with the criteria put forth by the CDC (Ex. 4B). For situations that meet certain CDC criteria, CDC recommends that employees receive a repeat TB skin test every 3 months, six months or annually, depending upon the risk assessment.

OSHA's proposed standard does not require a risk assessment of the type described by CDC and would extend coverage to worksites other than "health-care facilities" as described in the CDC document (Ex. 4B). Consequently, OSHA is proposing that repeat TB skin test be performed every 6 months or annually, depending upon the exposure determination. This testing frequency is expected to be both practical and effective in early identification of skin test conversions in the various worksites described in the Scope. The requirements for more frequent TB skin tests (e.g., 3 months after an exposure incident, or if deemed necessary by a licensed health care professional) ensures that employees' health is not compromised.

An exemption to this annual testing is permitted for an employer who can demonstrate that his or her facility or work setting: (1) Does not admit or provide medical services to individuals with suspected or confirmed infectious TB, (2) has had no cases of confirmed infectious TB in the past 12 months, and (3) is located in a county that, in the past two years, has had 0 cases of

confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. In these settings only a baseline TB skin test is required. This is discussed earlier under paragraph *b*, *application*.

Paragraph (g)(3)(i)(B) requires that, when an employee has signs or symptoms of TB, either observed or self-reported, the employee be provided a medical history, physical examination, TB skin testing, medical management and follow-up, and other related tests and procedures determined to be necessary. CDC states that the presence of signs or symptoms of tuberculosis in the employee requires prompt medical evaluation (Ex. 7-52, 7-93), and such evaluation provides an opportunity for initiating drug therapy. Furthermore, identifying those with infectious pulmonary TB disease enables the employer to remove them from the workplace, preventing exposure of other employees.

Paragraph (g)(3)(i)(C) requires that when an employee incurs an exposure incident, a medical history, TB skin testing, medical management and follow-up, and, if indicated, a physical examination and other related tests and procedures be provided. Evaluation and follow-up after each exposure incident help detect any resultant infections, as well as prevent infection in other employees, benefitting the health of all employees.

Following exposure, infected workers will usually develop a positive response to a TB skin test (Exs. 7-50, 7-93, 5-4). In certain cases, workers may also display signs or symptoms compatible with tuberculosis disease such as complaints of persistent cough (over 3 weeks in duration), bloody sputum, night sweats, weight loss, loss of appetite or fever. Use of the TB skin test has been recognized as a tool in the early identification of infection and for disease surveillance and follow-up. In paragraph (g)(3)(i)(C), the proposed standard also requires employers to provide testing for employees as soon as feasible after an exposure incident, unless a negative TB skin test has been documented within the preceding 3 months. If this baseline skin test is negative, another TB skin test shall be repeated 3 months after the exposure incident.

In order to accurately determine if an exposure incident has resulted in infection, the employer must first know the baseline skin test status of the affected employee(s) at the time of the exposure incident. Typically, skin test conversion can be documented approximately 2-10 weeks following

infection (Ex. 7-52). Consequently, it can be reasonably assumed that a negative TB skin test within the three months prior to the incident is sufficiently indicative of the employee's status at the time of the exposure incident.

For those employees who do not have a documented negative skin test within the past three months, the employer must determine their TB skin test status as soon as feasible after the exposure incident. The requirement of "as soon as feasible" in the provision puts the employer under the obligation of performing the TB skin test quickly, i.e., before infection resulting from the exposure would be manifested as a conversion. This assures that a true indication of the employee's skin test status at the time of the incident is obtained.

The purpose of the initial TB skin test following an exposure incident is to establish the TB skin test status of the employee(s) at the time of the incident. From this baseline, changes in TB skin test status can be identified. This initial test would not detect infection resulting from the exposure, since there would not have been sufficient time for conversion to occur. Hence, the employer is required to provide a repeat TB skin test three months after the exposure incident to determine if infection has occurred. This requirement reflects current CDC recommendations (Ex. 4B).

Paragraph (g)(3)(i)(D) requires that when an employee has a TB skin test conversion, the employee receive a medical history, a physical examination, medical management and follow-up, and other tests and procedures determined to be necessary. This provision assures that employees with skin test conversions receive appropriate evaluation for preventive therapy and for infectious tuberculosis. OSHA included the provision for early identification of disease since, as the CDC has stated in their guidelines, infectious tuberculosis disease can be prevented by the early treatment of tuberculosis infection.

In paragraph (g)(3)(i)(E), the proposed standard requires employers to provide TB skin testing within 30 days prior to termination of employment. The rationale for this requirement is two-fold. First, this requirement permits employees whose employment is terminated after an unrecognized exposure incident, but before their next regularly scheduled TB skin test, to determine their current (exit) TB skin test status. OSHA recognizes that in some instances employees may be in the process of converting from negative to

positive TB skin test results at the time of the exit testing and that some of these cases will be missed. Also missed will be employees who decline testing or who vacate their position immediately or without notice. While such situations are possible, the Agency believes that these occurrences would be rare. Secondly, by detecting recent conversions, appropriate steps can be taken by the employer to investigate the cause of the exposure. This helps prevent future exposures in those areas or situations where the exiting employee's infection may have occurred.

Paragraph (g)(3)(i)(F) requires that a medical history, physical examination, TB skin testing, determinations of the employee's ability to wear a respirator, medical management and follow-up or other related tests and procedures be conducted at any other time determined necessary by the physician or other licensed health care professional, as appropriate. This allows the physician or other licensed health care professional, as appropriate, to recognize the individual differences in employees' medical status and response to TB infection and increase the frequency or content of examination as needed. Some workers who have certain health conditions may need more frequent evaluation (Ex. 4B). For example, individuals who have a condition that may interfere with an accurate interpretation of TB skin test results (e.g., the development of test anergy in an employee who is on chemotherapy for cancer treatment), may warrant more frequent evaluations because of the high risk for rapid progression to TB disease if he or she becomes infected. (Ex. 4B)

Paragraph (g)(3)(ii) sets forth provisions regarding employees who wear respirators. Paragraph (g)(3)(ii)(A) requires that a face-to-face determination of the employee's ability to wear the respirator be accomplished before initial assignment to a job with occupational exposure (or within 60 days of the effective date of the standard) and at least annually thereafter. As discussed above under explanation of terms, this is a verbal exchange to assess health factors that could affect the employee's ability to wear a respirator. An initial determination is made before assignment to a job requiring respirator use to assure that the employee's health factors have been properly evaluated prior to incurring exposure to *M. tuberculosis*. This determination must also be made annually to assure that no health conditions have arisen that might

limit an employee's ability to wear a respirator.

Such conditions may arise and be noted prior to the annual determination. For example, the employee may experience unusual difficulty while being fitted or while using the respirator. In these situations, it is not appropriate to wait until the annual determination. Therefore, paragraph (g)(3)(ii)(B) requires that a face-to-face determination of the employee's ability to wear a respirator, including relevant components of a medical history and, if indicated, a physical examination and other related tests and procedures, be provided whenever the employee experiences unusual difficulty while being fitted or while using a respirator.

Paragraph (g)(3)(iii) requires employers to provide TB skin tests every 6 months for each employee who enters AFB isolation rooms or areas, performs or is present during the performance of high-hazard procedures, transports or is present during the transport of an individual with suspected or confirmed infectious TB in enclosed vehicles, or works in intake areas where early identification is performed in facilities where 6 or more individuals with confirmed infectious TB have been encountered within the past 12 months. OSHA believes that employees who perform these activities are exposed more intensely and frequently to individuals with suspected or confirmed infectious tuberculosis and should, therefore, be tested more frequently.

#### (4) Additional Requirements

Paragraph (g)(4) (i) through (iv) contain the additional requirements an employer must meet. Paragraph (g)(4)(i) requires that the physician or other licensed health care professional, as appropriate, verbally notifies the employer and the employee as soon as feasible if an employee is determined to have suspected or confirmed infectious tuberculosis. In this way an infectious employee can be removed from the workplace, thereby minimizing occupational exposure for other workers. Paragraph (g)(7)(i), Written Opinion, allows 15 days before the employer must provide the employee with the written opinion of medical evaluations from the physician or other licensed health care professional, as appropriate. In situations where an employee is determined to be potentially infectious, this time period leads to unnecessary delays in removal from the workplace and disease treatment. Therefore, OSHA requires the verbal notification to expedite treatment

and prevent spread of disease to other employees.

The proposed standard, in paragraph (g)(4)(ii), requires the employer to notify each employee who has had an exposure incident when the employer identifies an individual with confirmed infectious TB who was previously unidentified. For example, if a newly admitted patient undergoes diagnostic and therapeutic evaluation for suspected pulmonary malignancy, and the diagnosis of infectious tuberculosis is not made until several days after hospitalization, all hospital staff who have had exposure must be identified and provided TB skin test and follow-up. OSHA intends to assure that employees are provided with opportunities for early detection of tuberculosis infection. These provisions are consistent with the general purpose of tuberculosis medical surveillance as recommended by the CDC, and they are included to assist all employees in receiving the full benefits provided by the standard.

Determination of the drug susceptibility of the *M. tuberculosis* isolate from the source of an exposure incident resulting in a TB skin test conversion is required by paragraph (g)(4)(iii) unless the employer can establish that such a determination is infeasible. Information regarding drug susceptibility assists the examiner in deciding the most effective treatment therapy for the exposed employee, particularly if the source is a drug resistant strain of *M. tuberculosis*. Drug susceptibility testing of the source isolate is recommended by CDC (Ex. 4B). OSHA includes the provision regarding infeasibility because certain TB skin test conversions may involve unknown exposure sources. This can make identification of the isolate and therefore drug susceptibility testing infeasible or even impossible. It is the responsibility of the employer to establish that this is infeasible, if such is the case. Employers must make a good faith effort to identify *M. tuberculosis* isolates and obtain the drug susceptibility testing.

Paragraph (g)(4)(iv) requires the employer to investigate and document the circumstances surrounding an exposure incident or TB skin test conversion and to determine if changes can be instituted that will prevent similar occurrences in the future.

The provision assures that employers obtain feedback regarding the circumstances of employee exposures and use the information to eliminate or decrease specific circumstances leading to exposure. For example, exposure incident investigation shows that an

employee was exposed to tuberculosis as a result of recirculation of air containing infectious droplet nuclei. Further investigation shows inadequate local or general ventilation in the workplace. The employer can now repair the ventilation system and prevent future exposure incidents. Another example of corrective measures may be including a stronger training emphasis on certain procedures where proper work practices might have decreased the likelihood of transmission of tuberculosis. Employers can obtain further guidance regarding investigations for TB skin test conversions and exposure incidents in health care workers by reading the 1994 CDC guidelines.

#### (5) Medical Removal Protection

Paragraph (g)(5)(i) requires that employees with suspected or confirmed infectious tuberculosis be removed from the workplace until determined to be non-infectious according to current CDC recommendations. Infectious TB is contagious and removal is essential for the protection of other workers. An employee's "infectiousness" is determined by the physician or other licensed health care professional, as appropriate, who informs the employer as required in paragraphs (g)(4)(i) and (g)(7) of this section.

Paragraph (g)(5)(ii) states that for employees removed from the workplace under paragraph (g)(5)(i), the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the right to former job status, as if the employee had not been removed from the job or otherwise been medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first. Paragraph (g)(5)(iii) provides medical removal protection for employees removed from the workplace under paragraph (f)(4)(viii) of Respiratory Protection. The provision requires the employer to transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required. OSHA requires that if no such work is available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for 18 months, whichever comes first.

The requirement referring to the employee's right to return to his or her former job is not intended to expand upon or restrict any rights an employee has or would have had, to a specific job

classification or position under the terms of a collective bargaining agreement. Where the employer removes an employee from exposure to tuberculosis, the employee is entitled to full medical removal protection benefits as provided for under the standard.

The medical removal requirement is an indispensable part of this standard. The medical removal protection helps assure that affected employees participate in medical surveillance and seek appropriate care. If employees fear losing their jobs as a result of their medical condition they may attempt to hide the illness, thereby infecting many more workers and other people and jeopardizing their own health. The requirement for medical removal assures that an infectious employee will not be terminated, laid off, or transferred to another job (possibly at a lower pay grade) upon returning to work. Consequently, this protection should reduce reluctance on the part of the employee to participate in medical surveillance. The employee's health will be protected and the health of co-workers and others who come into contact with that employee will be protected, also.

OSHA believes that the cost of protecting worker health to the extent feasible is an appropriate cost of doing business since employers are obligated by the OSH Act to provide safe and healthful places of employment. Consequently, the costs of medical removal, like the costs of respirators and engineering controls, are borne by employers rather than individual workers.

If a removed employee files a claim for workers' compensation payments for a tuberculosis-related disability, then the employer must continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation may be reduced by such amount. The employer's obligation to provide medical removal protection benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer which was made possible by virtue of the employee's removal.

Medical removal should not be viewed as an alternative to primary control (prevention) of workers' exposure to tuberculosis; rather, it should be used as a secondary means of

protection, where other methods of control have failed to protect. The stipulation of an 18 month time period of protection is consistent with other OSHA standards (e.g., Cadmium, 29 CFR 1910.1027; Lead in Construction, 29 CFR 1926.62). The provision of medical removal and the costs associated with the program may indirectly provide employers with economic incentives to comply with other provisions of the standard. It can be expected that the costs of medical removal will decrease as employer compliance with other provisions of the standard increases.

#### (6) Information Provided to Physician or Other Licensed Health Care Professionals

Paragraph (g)(6)(i) requires the employer to assure that the health care professionals responsible for the medical surveillance receive a copy of this regulation. OSHA believes it is the employer's responsibility to inform the health care professionals responsible for medical surveillance of the requirements of this standard. This will help assure that these individuals are aware of and implement the requirements. This provision is included in other OSHA standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(6)(ii) requires the employer to assure that the physician or other licensed health care professional, as appropriate, evaluating an employee after an exposure incident receives: (A) A description of the exposed employee's duties as they related to the exposure incident; (B) a description of the circumstances under which the exposure incident occurred; (C) the employee's diagnostic test results, including drug susceptibility pattern, or other information relating to the source of exposure that could assist in the medical management of the employee; and (D) all of the employee's medical records relevant to the medical evaluation of the employee, including TB skin test results. Since the individual responsible for medical surveillance may not necessarily be the person evaluating an employee after an exposure incident, it is necessary to also provide a copy of this standard to the evaluating physician or other appropriate licensed health care professional, as required by paragraph (g)(6)(i). In this way, the evaluator will also be informed of and implement the standard's requirements. All of the above information is essential to follow-up evaluation, and helps assure that an accurate determination can be made regarding appropriate medical treatment

of the exposed employee. This provision is consistent with other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030, Benzene, 29 CFR 1910.1028).

#### (7) Written Opinion

Paragraph (g)(7)(i) states that the employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section. The purpose of requiring the employer to obtain a written opinion is to assure that the employer is provided with documentation that the medical evaluation of the employee (1) has taken place and that the employee has been informed of the results; (2) has included an evaluation of the employee's need for medical removal or work restriction; (3) describes the employee's TB skin test status so that the employer can assess action needed to prevent further exposure; and (4) informs the employer of the employee's infectivity status so that the employer can take action to prevent the employee from becoming a source of infection for other employees.

The employer has a right to know the information contained in the written opinion and may retain the original written opinion, but must provide a copy to the employee. The 15 day provision assures that the employee is informed in a timely manner regarding information received by the employer and is consistent with other OSHA standards (e.g., Formaldehyde, 29 CFR 1910.1048; Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

In addition, the written opinion is required to assure the employer that the employee has been provided with information about any medical conditions resulting from exposure to tuberculosis which require further evaluation or treatment.

OSHA believes it is important that employers know if their employees have had evaluations for tuberculosis infection or exposure incidents, and that physicians or other appropriate licensed health care professionals, acting as agents for the employer, have provided the employer with written documentation that these evaluations occurred. However, paragraph (g)(7)(ii) limits the information the employer is provided in order to protect the privacy of the employee. The requirement for a written opinion after a medical evaluation has been included in other OSHA standards (e.g., Occupational Exposures to Hazardous Chemicals in

Laboratories, 29 CFR 1910.1450; Formaldehyde, 29 CFR 1910.1048; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(7)(ii)(E) requires the written opinion to state any recommendations for medical removal or work restrictions and the employee's ability to wear a respirator. This recommendation must be in accordance with paragraphs (g)(5)(i) and (f)(5)(viii) of this section. Including this information in the written opinion assures that the employer is provided with written documentation of the need for removal of an employee with infectious tuberculosis from the workplace. The provision also assures that the employer is aware of any work restrictions on the employee and the employee's ability or inability to wear a respirator. This information enables the employer to take appropriate steps in managing the employee's duties upon return to the workplace. OSHA recognizes the need for this provision and has included it in other standards (e.g., Lead in Construction, 29 CFR 1926.62).

Paragraph (g)(7)(iii) states that all other findings or diagnoses shall remain confidential and shall not be included in the written report. OSHA believes that all health care professionals have an obligation to view medical information gathered or learned during tuberculosis medical surveillance or post-exposure evaluation as confidential medical information. As stated previously, the maintenance of confidentiality encourages participation in medical surveillance by allaying employee concern that medical conditions unrelated to tuberculosis exposure will be communicated to the employer. OSHA also recognizes that successful medical surveillance and medical management and follow-up programs must guarantee this confidentiality, the specific requirements on confidentiality can be found in applicable state and federal laws and regulations that cover medical privacy and confidentiality. Finally, OSHA recognizes the need for this provision and has included it in other standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030).

#### *Paragraph (h) Communication of Hazards and Training*

Paragraph (h), Communication of Hazards and Training, addresses the issues of transmitting information to employees about the hazards of tuberculosis through the use of labels, signs, and information and training. These provisions apply to all operations that come under the coverage of

paragraph (a), *Scope*, of this section. Although OSHA has an existing standard, Hazard Communication (29 CFR 1910.1200), which requires an employer to inform employees about the hazards of chemical substances they are exposed to occupationally, that standard does not apply to biological hazards such as TB. Consequently, it is OSHA's intent in this paragraph to assure that employees will receive adequate warning through labels, signs, and training so that the employee understands the hazard and can take steps to eliminate or minimize his or her exposure to tuberculosis.

Paragraphs (h)(1) and (h)(2) of the proposed standard for tuberculosis provide the specific labeling and sign requirements that are to be used to warn employees of hazards to which they are exposed. The requirements for labels and signs are consistent with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of occupational hazards. As noted in paragraphs (c)(2)(v), (d)(3), and (d)(5) above, settings where home health care and home-based hospice care are provided are not required to have engineering controls and, therefore, the signs and labeling would not be required in these cases.

#### Labels

Paragraph (h)(1)(i) requires that air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* must be labeled at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and discharge outlets of non-HEPA filtered direct discharge systems. The label must state "Contaminated Air—Respiratory Protection Required." The provision for labeling of air ducts that may reasonably be anticipated to contain aerosolized *M. tuberculosis*, with the proposed hazard warning, is supported by the CDC in its discussion of HEPA filter systems. This discussion states:

Appropriate respiratory protection should be worn while performing maintenance and testing procedures. In addition, filter housing and ducts leading to the housing should be labeled clearly with the words "Contaminated Air" (or a similar warning). (Ex. 4B)

The intent of this provision is to assure that employees who may be accessing these systems for the purposes of activities such as maintenance, replacement of filters, and connection of additional ductwork are warned of the presence of air that may contain aerosolized *M. tuberculosis* so that appropriate precautions can be taken.

Consequently, labels are to be placed at all points where these systems are accessed.

In situations where air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is discharged directly to the outside, the exhaust outlets are also to be labeled. This is especially important since these outlets will most likely be at a remote location from the contaminated air source. Employees working in these locations would have no warning of the hazard if these ducts were not labeled. In addition, a number of exhaust outlets from a variety of sources may be present in an area (e.g., a hospital roof). In such situations, labeling also serves to distinguish contaminated air exhaust outlets from others in the vicinity.

The proposed provision does not require that a symbol (e.g., "STOP" sign) be included on the duct labels. OSHA believes that, in many situations, the label will be stenciled onto the duct, similar to the labeling used on other piping and duct labels currently being employed in some of these facilities. In addition, the group of workers accessing ducts will likely be a well-defined, skilled group that can be trained to recognize the text's warning. However, OSHA seeks comment on whether a symbol on duct labels is necessary and any information regarding the current use of such symbols.

Paragraph (h)(1)(ii) requires that clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory must be labeled with the biohazard symbol or placed in a red container(s). This provision is intended to assure that employees are adequately warned that these containers require special handling. In addition, the label or color-coding serves as notice that certain precautions may be necessary should materials in the container be released (e.g., a spill). This provision closely follows the recommendations outlined in the CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 7-72) and is in accordance with the labeling requirements of paragraph (e)(2)(i)(D), Clinical and Research Laboratories, of this section.

#### Signs

Paragraph (h)(2) contains the provisions relative to the posting of warning signs in areas where employees may be exposed to droplet nuclei or other aerosols of *M. tuberculosis*. More specifically, paragraph (h)(2)(i)(A) requires that signs be posted at the

entrances to rooms or areas used to isolate an individual with suspected or confirmed infectious TB. The term "rooms or areas" is used in order to expand the requirement beyond the AFB isolation room or area. Throughout the course of a day various employees may enter such rooms or areas in order to carry out their duties. These employees can include physicians, nurses, respiratory therapists, housekeepers, and dietary workers. Posting a sign at the entrance of those rooms or areas where an individual with suspected or confirmed infectious TB is isolated serves to warn employees that entry into the room or area requires that certain precautions be taken. In addition, the employer may have implemented a program to minimize the number of employees who enter such rooms or areas. In this case, the sign serves as notice that entry may not be permitted for a particular employee or group of employees. As an additional public health benefit, such signs will also provide warning to visitors or family members who may be entering the area and are unaware of the hazard.

Paragraph (h)(2)(i)(B) requires that signs be posted at the entrances to areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB. Although it is critically important to provide appropriate warning to employees who may inadvertently enter an isolation room, other areas of the facility are of concern as well. Special treatment areas, such as bronchoscopy suites, respiratory therapy areas where cough-inducing procedures are performed, or radiology examination rooms may, at one time or another, be occupied by an individual with suspected or confirmed infectious TB. When individuals with suspected or confirmed tuberculosis are occupying these areas, the area must have signs placed at the entrances in order to warn employees of the hazard.

The risk of exposure to aerosolized *M. tuberculosis* also exists in clinical and research laboratories where specimens, cultures, and stocks containing the bacilli are present. Therefore, paragraph (h)(2)(i)(C) requires that a sign be posted at the entrance to laboratories where *M. tuberculosis* is present. Posting of such a sign is consistent with the recommendations of the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 7-72) and is in accordance with the sign posting requirement of paragraph (e)(2)(ii)(E), Clinical and Research Laboratories, of this section.

Even though a suspected or confirmed infectious individual is no longer present in a room or area, the droplet nuclei generated by that individual may continue to drift in the air.

Consequently, the air in the room or area presents a risk of TB infection until the droplet nuclei are removed. With this in mind, paragraph (h)(2)(ii) requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9%, to prevent entry without the use of respiratory protection [The rationale for specifying this removal efficiency has been discussed previously under paragraph (d), *Work Practices and Engineering Controls*]. This provision is supported by the CDC's current recommendations for tuberculosis control (Ex. 4B).

The CDC has published guidelines regarding the length of time for such sanitation of the room air based upon the air exchanges per hour (see Appendix C of this section). Requiring that the sign remain posted until the room or area is adequately ventilated will assure that unprotected employees do not inadvertently enter while an infection risk is still present.

Until such time as the room or area has been adequately ventilated, employees entering the area must wear respiratory protection. This paragraph is designed to address the situations where employees will be entering or using a room or area previously occupied by an individual with suspected or confirmed infectious TB before the room or area has been satisfactorily ventilated. For example, when an infectious tuberculosis patient is discharged from a facility and the room is needed for an incoming new patient, certain housekeeping and maintenance functions need to be done between patient occupancies. Employees who must perform the tasks required to prepare the room for the next patient must wear respiratory protection until such time as the room has been adequately ventilated, based upon the CDC criteria. Obviously, if the room was previously occupied by an individual with suspected infectious TB and that individual is medically determined to be noninfectious, it would not be necessary to ventilate the room to remove *M. tuberculosis* nor to continue to post a sign at the entrance to the room since there would be no tuberculosis bacilli present.

OSHA has given much consideration to what sign should be required for posting outside of isolation rooms or areas and for areas where procedures or services are performed on individuals with suspected or confirmed infectious TB. The purpose of the sign is to convey a uniform warning along with the necessary precautions to be used for the particular situation.

The sign recommended by the CDC in 1983 in their "CDC Guidelines for Isolation Precautions in Hospitals" (Ex. 7-112) read "AFB Isolation" and then listed the requirements for entry. However, the instructions on the CDC sign are different from OSHA's requirements. For example, the sign instructed workers that "Masks are indicated only when patient is coughing and does not reliably cover mouth", a recommendation that is currently outdated and no longer recommended by CDC. The document contained another sign for "Respiratory Isolation" but this sign was designed for use with a number of respiratory hazards (rubella, meningococcal meningitis, chickenpox) that are not addressed in OSHA's proposed standard. Neither the 1990 CDC tuberculosis guidelines (Ex. 3-32) nor the 1994 CDC tuberculosis guidelines (Ex. 4B) provided help with this issue. OSHA also considered using a sign having the words "AFB Isolation" however, there is some concern that "AFB Isolation" could compromise patient confidentiality. For example, that sign outside of a treatment area or isolation room would allow members of the public or employees with no "need to know" to discern the potential diagnosis of the individual being isolated.

In addition, OSHA was unable to find uniform recommendations about signs in sources outside of the CDC. A number of facilities use signs to warn employees of the hazard of TB, but these signs vary widely and often had been developed for a particular facility. Thus, facilities that were using TB warning signs did not appear to be universally applying a specific sign.

The Agency does not believe, however, that development of a sign should be left to individual employers since this could lead to a variety of signs that may not provide adequate warning of the hazard. In the work settings covered by the proposal, there are many employees who move from facility to facility or even from industry to industry. In fact, a substantial number, like contract nurses, will work in several facilities at one time. A universal sign will enable these employees to recognize the hazard wherever it occurs and then take proper

precautions. The issue of whether OSHA should specify colors that must be included on the sign was raised at TB stakeholder meetings. OSHA realizes there is a part of the population, perhaps as high as 10% of all men, that is color blind and that at some work sites some colors have been employed that are different from the red that OSHA proposes be used. However, stakeholders, particularly those whose jobs took them to several different work sites, urged OSHA to require a standardized sign and, of those who considered the issue, there was general agreement that the red on the familiar "stop" sign was appropriate. OSHA has preliminarily concluded that the colors required provide needed warning even though not all employees (e.g., those who are color blind) may benefit from them, and that the colors chosen are consistent with conventions on health signage. The Agency has developed a sign that it believes will provide appropriate warning and be easily recognizable. Failing to find either a guideline recommendation or a generally accepted community standard regarding what sign should be placed at the entrances to these areas, OSHA looked to generic, broad-based sources for symbols which would be easily identifiable, understandable to workers who were not able to read well or are non-English speaking, and simple to construct.

In paragraph (h)(2)(iii), therefore, OSHA is proposing that a "STOP" sign with the accompanying legend, "No Admittance Without Wearing A Type N95 Or More Protective Respirator", meets these criteria. The sign is easily recognizable, requires a simple color scheme, and should be understandable to employees with minimal training.

OSHA is seeking information on the effectiveness of the proposed sign to warn workers of the presence of a hazard, as well as information on other signs that may be more effective. Please be specific when providing information, keeping in mind the wide variety of work sites where signs will be needed. Where an alternative is being proposed, please enclose a model or drawing as well as the rationale for believing that it will be more effective than OSHA's proposed sign.

Paragraph (h)(2)(iv) requires that signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation

"*Mycobacterium tuberculosis*", and special requirements for entering the laboratory or autopsy suite. This provision has been taken directly from the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 7-72). As previously discussed, the purpose for this sign is to warn employees of the potential TB hazard and inform them of precautions that must be taken to prevent exposure.

#### Information and Training

It is OSHA's position that employees must understand the nature of the hazards in their workplace and the procedures to follow in order to eliminate or minimize their risks of exposure to these hazards. (Exs. 4-B, 7-169, 7-170, 7-61, 7-64) In the case of *M. tuberculosis*, employee exposures may result in a TB infection, which may ultimately result in disease and even death. The provisions in paragraph (h)(3) of this proposed standard set forth the training that each employer must provide to his or her employees. OSHA believes that effective training is a critical element in any occupational safety and health program. In this proposed standard, the employer would be required to provide training for each employee covered by the scope of the standard.

Paragraph (h)(3)(i) requires that employers assure that each employee with occupational exposure participates in training, which must be provided at no cost to the employee and be made available at a reasonable time and place. Since appropriate training is considered to be critical in assuring employee protection, the employer is responsible for making sure that each employee with occupational exposure participates in the training program. Having the employee pay in some manner for all or part of the training or requiring the employee to attend training at an unreasonable time and place would be a disincentive to participation. If training cannot feasibly be provided during work hours, employees are to be paid for training scheduled outside of normal working hours.

In view of the importance of training, OSHA is proposing that it be provided at several particular points in time. (Exs. 7-169; 4-B) More specifically, paragraph (h)(3)(ii) requires that training be provided: (A) before initial assignment to tasks where occupational exposure may occur, for those employees without previous occupational exposure; (B) within 60 days after the effective date of the final standard, for those employees who have occupational exposure at the time of the standard's promulgation; and (C) at least

annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii). The employer must provide re-training to an employee in any of the topic(s) in paragraph (h)(3)(vii) in which that employee cannot demonstrate the necessary knowledge and/or skill. This approach to training frequency assures that employees entering jobs with occupational exposure will be fully trained before exposure occurs. In addition, employees who are already working in jobs with occupational exposure at the time of the standard's promulgation will receive training and must become knowledgeable in all of the required aspects of the standard (e.g., employer's exposure control plan, medical surveillance program, warning signs and labels) within a short period of time.

Annual re-training reinforces the initial training and provides an opportunity to present new information that was not available at the time of initial training. The Agency recognizes that, as a result of training previously provided by the employer, employees may possess some of the knowledge and skills listed in the training topics in paragraph (h)(3)(vii). Consequently, OSHA is proposing that re-training be provided annually unless the employer can demonstrate that the employee has the specific knowledge and skills required by this paragraph. The employer must provide re-training to an employee in any topic(s) in paragraph (h)(3)(vii) in which the employee cannot demonstrate specific knowledge and skills.

An employee with occupational exposure to TB who moves to a job with another employer that also involves occupational exposure to TB would not need to meet all of the initial training requirements. In such instances, the Agency has determined that the employee's prior training in the general topics required by the standard (e.g., the general epidemiology of tuberculosis, the difference between tuberculosis infection and tuberculosis disease) would remain relevant in the new work setting and that the new employer need not re-train in these topics. However, the employee would not possess knowledge of the topics required by the standard that are specific to the new employer's particular work setting (e.g., the new employer's exposure control plan and respiratory protection program and the means by which the employee could access the written plans for review). OSHA is proposing to permit limited "portability" of training, as noted in the standard. This note states

that training in the general topics listed in paragraph (h)(3)(vii) that has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics listed in paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h) (e.g., at no cost to the employee and at a reasonable time and place).

OSHA is aware that some employers have already established training for their occupationally exposed employees. (Ex. 7-169) In light of this, paragraph (h)(3)(iii) of the proposed standard requires only that limited training be conducted for those employees who already have received training on tuberculosis in the year preceding the effective date of the standard. The additional training would only have to address those provisions of the standard not previously covered in the earlier training.

The requirement for annual training within one year of the employee's previous training, in paragraph (h)(3)(iv), assures that each employee receives training within 12 calendar months of his or her last training. Annual training is not based on a calendar year; that is, training will not be permitted to be provided to an employee in January of one year and in December of the following year, essentially a 23-month span between training sessions. Employers may establish schedules for training around this requirement.

Also, paragraph (h)(3)(v) stipulates that the employer must provide additional training whenever changes in the occupational environment, such as modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure to *M. tuberculosis*. This provision will assure that employees remain apprised of any new exposure hazards and the precautions necessary to protect themselves from exposure. This additional training does not need to entail a complete reiteration of the annual training, but may be limited to addressing the new sources of potential exposure.

The proposed standard requires that training material be used that is appropriate in content and vocabulary to the educational level, literacy and language of employees. Employees must be able to comprehend the information being conveyed in order for it to be useful. Therefore, the employer has the responsibility for assuring that the training is provided in an understandable manner to the audience being addressed. This provision would

assure that employees, regardless of their educational or cultural background, will receive adequate training.

Paragraph (h)(3)(vii) of the proposed standard contains the specific elements that would comprise a minimum training program. (Exs. 4-B; 7-169; 7-64) The provisions for employee training are performance oriented, stating the categories of information to be transmitted to employees and not the specific ways that this is to be accomplished. This assures that important information is communicated to employees about the nature of this occupational hazard while allowing employers the most flexible approach to providing training. OSHA has set forth the objectives to be met and the intent of training. The specifics of how the employer assures that employees are made aware of the hazards in their workplace and how they can help to protect themselves are left up to the employer who is best qualified to tailor the training to the TB hazards in his or her workplace.

The proposed standard would require the employer to explain a number of particular topics in the training session(s). Paragraph (h)(3)(vii)(A) requires the employer to provide an explanation of the contents of this standard and the location of an accessible copy of the regulatory text and appendices to this standard. This enables the employee to have access to the standard and to become familiar with its provisions. It is not necessary for the employer to provide each employee with a copy of the standard; it is sufficient for the employer simply to make a copy accessible. For example, a copy of the standard could be posted in a location where it could be readily and easily viewed by employees.

An important element in the training involves an overview of the epidemiology of tuberculosis, the pathogenesis of the disease and an explanation of various aspects of risk to employees. (Ex. 4B) More specifically, paragraph (h)(3)(vii)(B) requires that the training include an explanation of: the general epidemiology of tuberculosis, including multidrug-resistant TB and the potential for exposure in the facility; the signs and symptoms of TB, including the difference between TB infection and TB disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase an employee's risk of developing TB disease if infected.

Since the employer can tailor the training to the needs of his or her

employees, the training program will likely be more technical for some audiences and less technical for others. The general goal of this paragraph is to assure that each employee being trained understands what tuberculosis is, how it is spread, and possible risks that may affect the employee.

Employees need to be able to recognize symptoms associated with TB disease. (Ex. 4B) The employee must understand that certain symptoms (e.g., a persistent cough lasting 3 or more weeks, bloody sputum, night sweats, anorexia, weight loss, fever) may be related to TB. In addition, information on non-occupational risk factors that place employees at increased risk of developing tuberculosis disease following an infection permits those individuals at increased risk to make informed decisions about their employment situations.

Paragraph (h)(3)(vii)(C) requires an explanation of the employer's exposure control plan and respiratory protection program. Employees must also be informed about what steps they need to take to review the written plans, if they so desire.

Paragraph (h)(3)(vii)(D) requires the employer to train employees regarding the tasks and other activities that may involve occupational exposure to tuberculosis. Employees must be made aware of those job duties which may expose them to tuberculosis. For example, although certain health care professionals may easily recognize the hazard involved in transporting a person with infectious TB, the staff of a correctional facility may not. On the other hand, some health care professionals may not immediately recognize that their mere presence in a room where an individual with suspected or confirmed infectious TB is being X-rayed presents an exposure risk and necessitates wearing a respirator. All occupationally exposed employees need training that will enable them to recognize those activities that put them at risk of exposure.

Paragraph (h)(3)(vii)(E) of this section requires employers to train employees regarding both the uses and limitations of various control measures, specifically those used at the employees' worksite. Exposed employees must be familiar with the employer's tuberculosis policies and procedures in order for them to be properly implemented. Control of exposure frequently involves using a variety or combination of engineering controls, administrative controls, work practice procedures and personal protective equipment. To assure that employees will be able to identify and implement methods of

reducing occupational exposure to tuberculosis, they must understand how these controls are applied in their work sites and the limitations thereof. With this understanding, employees will be more likely to use the appropriate control for the situation at hand and to use it correctly. For example, employees must be able to recognize the labels and signs used to identify rooms or areas where suspected or confirmed infectious individuals are present so that they can take appropriate precautions before entering. Understanding of the limitations of control measures will also enable employees to recognize when inappropriate or inadequate control measures have been taken and increases the likelihood that they will report such situations.

Training must be relevant to the specific site where the employee will be working. Each employee must know, for example, the procedures used in his or her particular facility to identify suspected infectious TB cases, where respiratory protection is kept, and what engineering controls are in place within the facility. This training is particularly important for workers who move between several facilities in the course of their work, for example, "leased" personnel, part-time employees, "moonlighters", or contractors.

The provision covering the selection, types, proper use, location, removal and handling of respiratory protection, paragraph (h)(3)(vii)(F), is particularly important because many of the employees and employers proposed to be covered by the tuberculosis standard may not be accustomed to the use, selection, and upkeep of respiratory protection. Consequently, training on aspects such as the necessity for respiratory protection, the appropriate type of respiratory protection, where to obtain it, and its proper use, fit, and the general upkeep is necessary to assure the effectiveness of respirator use. (Ex. 7-64)

OSHA believes that employees who have a clear understanding of the medical surveillance program (its purpose, methodology, and the significance of the results of examinations and tests), will be much more likely to participate in that program. Therefore, paragraph (h)(3)(vii)(G) requires that the training include an explanation of the employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program. This increased participation by trained

employees helps the employee to identify changes in his or her personal health status and also aids the employer in assessing the effectiveness of his or her TB control program.

Each employee must understand the actions to be taken if an occupational exposure occurs as well as what is available to them regarding appropriate medical treatment, prophylaxis, and post exposure follow-up in order for the employee to lessen the chance of developing active disease. Therefore, paragraph (h)(3)(vii)(H) would require an explanation of the procedures to follow if an exposure incident occurs, including the method of reporting the incident, an explanation of the medical management and follow-up that the employer is required to provide, and the benefits and risks of drug prophylaxis. In addition, the employee must be provided with an explanation of the procedures to follow if the employee develops signs or symptoms of tuberculosis disease [paragraph (h)(3)(vii)(I)]. In this way, an employee who notes the signs or symptoms of personal disease development will be aware of the appropriate steps to take, thereby speeding initiation of medical evaluation. Quick evaluation protects the employee, co-workers, and the public.

In paragraph (h)(3)(viii), the proposed standard mandates that the person conducting the training must be knowledgeable in the subject matter as it relates to the specific workplace being addressed. OSHA believes that a variety of persons are capable of providing effective training to employees. OSHA has approached this section of the proposed standard in much the same way as the trainer requirements were addressed in the standard for Occupational Exposure to Bloodborne Pathogens. That is, a knowledgeable trainer is one who is able to demonstrate expertise in the area of the occupational hazard of tuberculosis and is familiar with the manner in which the elements of the training program relate to the particular workplace.

A number of resources are available through the Centers for Disease Control and Prevention and professional organizations such as the American Lung Association and the American Thoracic Society that can be used to educate trainers and prepare them for this task. In addition, specialized training courses in the area of tuberculosis control can also assist in educating trainers (Ex. 7-189).

In addition to general knowledge of the subject matter, it is important that the trainer be able to instruct the participants in site-specific features of

the Exposure Control Plan that will reduce their risk in the particular facility. This benefits not only employees within the facility but also provides temporary employees with the information needed to protect themselves against exposure while working in the facility. For example, workers who have received general training by their employer (e.g., a personnel staffing agency) will also receive training about the facility where they will actually perform their duties (e.g., a specific hospital).

An important component of an effective learning experience is the opportunity for the learner to interact with the trainer for the purposes of asking questions and obtaining clarification. Paragraph (h)(3)(ix) would require that the employer provide employees with this opportunity as part of the training program. The trainer must be available at the time that the training takes place. OSHA would expect that in most instances, the individual who would provide answers to the employee's question would be physically present when the employee is trained. The Agency does recognize, however, that there may be some instances where this is not possible. In these cases, it would be acceptable for the employee to ask questions by telephone.

An employer would not be expected to train employees in site-specific topics that are not applicable to the employer's work setting. For example, if a facility was not required by the standard to utilize engineering controls, the employer would not be responsible for training his or her employees about the various aspects of engineering controls.

OSHA believes that the information and training requirements incorporated into this proposed standard are needed to inform employees about the hazard of tuberculosis and to provide employees with an understanding of the degree to which they can minimize the health hazard. Training is essential to an effective overall hazard communication program and serves to explain and reinforce the information presented to employees on signs and labels. These forms of information and warning will be meaningful only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposure.

OSHA seeks comment on the proposed content of the training program and requests that model TB training programs be submitted to the docket, particularly those designed for audiences whose participants may have language difficulties or have no health care background, and those that have

been judged to be successful in communicating information to employees. It is OSHA's intent, upon publication of the final standard, to include information on training programs in compliance guides to be developed for small entities.

#### *Paragraph (i) Recordkeeping*

This proposed standard requires employers to keep records related to TB, including medical surveillance and training records for all employees with occupational exposure and engineering control maintenance and monitoring records. OSHA has made a preliminary determination that, in this context, medical and training records are necessary to assure that employees receive appropriate information on hazards and effective prevention and treatment measures, as well as to aid in the general development of information on the occupational transmission of TB. Specifically, OSHA believes that maintenance of medical records is essential because documentation is necessary to ensure proper evaluation of an employee's infection status and for prompt and proper healthcare management following an exposure incident. OSHA has also preliminarily determined that maintenance and monitoring records for engineering controls are necessary for two reasons: to enable the employer to know that the control methods remain in good working order so as to assure their effectiveness and to aid the Agency in enforcement of the standard.

In paragraph (i)(1), OSHA proposes to require employers to establish and maintain a medical record in accordance with 29 CFR 1910.1020 for each employee with occupational exposure to TB. The record must include: (A) The name, social security number, and job classification of the employee; (B) A copy of all results of examinations, medical testing, including the employee's tuberculin skin test status; and follow-up procedures required by paragraph (g); (C) The employer's copy of the physician's or other licensed health care professional's written opinion as required by paragraph (g)(7); and (D) A copy of the information provided to the physician or other health care professional required by paragraph (g)(6). The information that must be included in the medical record is necessary for the proper evaluation of the employee's infection status and management of occupational exposure incidents. This record will aid OSHA in enforcing the standard and the information therein, when analyzed, will further the development of health

data on the causes and prevention of occupational transmission of TB. Similar provisions for collection and retention of such information have been included in other OSHA health standards including, most recently, Bloodborne Pathogens (29 CFR 1910.1030) and Cadmium (29 CFR 1910.1027).

In paragraph (i)(1)(iii), OSHA is proposing to require that the employee medical records be kept confidential and not be disclosed or reported to anyone without the employee's express written consent except as required by section i or as may be required by law. In nearly every health standard rulemaking, employees have told the Agency that keeping medical records confidential is extremely important to them. Employees stated that, without assurance of confidentiality, they would be reluctant to participate in medical surveillance, a predicament that would be detrimental to their health and could affect health and safety conditions in the workplace. During the Bloodborne Pathogens rulemaking, confidentiality of medical records was a major issue due to the nature of the diseases addressed. Of particular concern was keeping the medical records from being disclosed to the employer. It was explained in the Bloodborne Pathogens standard and is applicable here that such confidentiality can be accomplished by having the records kept by the physician or other licensed health care provider at the expense of the employer. In those cases where the employer is the health care provider, the records can be maintained separately from other employee records so that disclosure can be strictly limited to the physician or other licensed health care professional and his or her staff who are responsible for the medical management of the employee. It was pointed out in the preamble to the Bloodborne Pathogens standard, and bears repeating here, that the confidentiality provisions in the proposed standard are reiterations of existing standards of conduct in the health care professions and that the OSHA requirements do not abridge, enlarge or alter existing ethical or statutory codes (56 FR 64170). This section of the proposal requires that medical records be disclosed to the Assistant Secretary or the Director (of NIOSH) and as may be required by law, which means that this proposed standard would not prevent employers from reporting TB cases to federal, state, or municipal health departments where that reporting is required by law.

Paragraph (i)(1)(iv) proposes to require that medical records be maintained in accordance with 29 CFR

1910.1020 for at least the duration of employment plus 30 years. The Access to Medical Records Standard contains an exception to the 30-year requirement that provides that the medical records of an employee who has worked less than one year must be maintained throughout his or her employment, but need not be retained afterwards as long as they are given to the employee upon termination of employment. Maintaining the records for the duration of employment serves several purposes: the records can provide valuable information to the employee's healthcare provider; the records enable the employer to know that employees are benefitting from regular surveillance and timely intervention following occupational exposure to TB; analysis and aggregation of the records can provide insight into the causes and consequences of occupational exposure to TB; and, the records will aid in the enforcement of the standard. Requiring the records to be kept 30 years beyond employment is necessary because TB can have a long incubation period, with disease often appearing only many years after initial infection. This retention time is also consistent with other OSHA health standards (See for example Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030; Ethylene Oxide, 29 CFR 1910.1047).

In paragraph (i)(2), OSHA proposes to require employers to record TB infection and disease in accordance with 29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses, and 29 CFR 1960, the equivalent requirement for Federal Agency programs. This should not be an unfamiliar requirement to employers because occupational TB infections and disease must be reported in accordance with 29 CFR 1904 and 29 CFR 1960, as directed by current OSHA enforcement policy (Ex. 7-1).

In paragraph (i)(3), OSHA proposes to require training records, which include: (A) The dates of the training sessions; (B) The contents or a summary of the training sessions; (C) The names and qualifications of persons conducting the training; and (D) The name and job classification of all persons attending the training sessions. This requirement is consistent with other OSHA standards, particularly Bloodborne Pathogens, and it represents the minimum amount of information an employer, an employee, or an OSHA compliance officer would need in order to determine when and what training had been provided, who administered it and who attended. Additionally, such a record is an invaluable aid to the

employer when evaluating his or her training program.

OSHA proposes, in paragraph (i)(3)(ii) to require that training records be maintained for three years beyond the date the training occurred. The Agency anticipates that employers will not have difficulty maintaining the records for three years because the information to be included is not extensive and many employers are already keeping training records three years as required by other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030). Moreover, these records are not required to be kept confidential and so may become part of an employee's personnel file or part of a larger file, at the discretion of the employer.

In paragraph (i)(4), OSHA proposes to require engineering control maintenance and monitoring records be kept that include: (A) Date; (B) Equipment identification; (C) Task performed; and (D) Sign-off. The performance monitoring records must include: (A) Date and time; (B) Location; (C) Parameter measured; (D) Results of Monitoring; and (E) Sign-off. Only two of these items will require more than a few words or numbers to record; the two items that require more extensive information are the maintenance task performed and the results of the performance monitoring. Where the employer has not already developed a method for recording the task performed, the maintenance person can list the tasks or use a previously prepared check-list. The results of performance monitoring can be recorded in the same way or another way that meets the needs of the particular workplace so long as it includes all of the information required by the paragraph. OSHA believes that the information in these records is the usual data that are generated by persons maintaining and servicing equipment so that the status of the equipment and its effectiveness can be known for a given time. The information is also useful in determining when further servicing is needed.

Proposed paragraph (i)(4)(iii) requires engineering control maintenance and monitoring records to be maintained for three years. The three year period is a reasonable period of time and it will enable the employer to develop and sustain a proper maintenance program and to track the effectiveness of the controls. Moreover, the records will aid the OSHA compliance officer in enforcing the standard's requirements for engineering controls.

Availability of medical records is specified in section 8(c) of the Act. In paragraph (i)(5) of this standard, OSHA

proposes to restrict the availability of employee medical records while making employee training records and engineering control and monitoring records generally available upon request. Medical records must be provided to the subject employee, to anyone having written consent from the employee, to the Director and to the Assistant Secretary in accordance with 29 CFR 1910.1020, which sets forth the procedures that will protect the privacy concerns of the employees. This paragraph does not affect existing legal and ethical obligations concerning maintenance and confidentiality of employee medical records. An employer's access is governed by existing federal, state and local laws and regulation. This standard, like Bloodborne Pathogens (29 CFR 1910.1030) and other OSHA standards, limits employer access to confidential information while allowing the employer access to the information needed to make appropriate decisions relative to his or her medical surveillance program. For example, paragraph (g)(7)(ii) limits the information that can be included in the physician's or other licensed health care professional's written opinion and paragraph (g)(7)(iii) requires that other medical diagnoses or findings be kept confidential. There is no language in this proposed standard that grants an employer access to the confidential information in an employee's medical file. OSHA illness and injury records are accessible under 29 CFR 1904 and 29 CFR 1960, as appropriate, to the facility. In this proposal, as in OSHA's other health standards, training records and engineering control maintenance and monitoring records are to be provided upon request to the employees, their representatives, the Director and the Assistant Secretary. Employers should not have difficulty complying with this provision because most will have experience with such recordkeeping from other standards. There are no confidentiality issues raised by these records.

In paragraph (i)(6), an employer who goes out of business is required to transfer medical records as set forth in 29 CFR 1910.1020(h) and 29 CFR 1904, which address the transfer of medical records. Specifically, medical records must be transferred to a successor employer who must accept them and keep them in accordance with the requirements of 29 CFR 1910.1020. In the event the employer ceases to do business and there is no successor employer, the employer is required to notify the Director, at least three months

prior to disposal of the records, and transmit them to the Director if required by the Director to do so. This is consistent with other health standards and ensures that a successor employer (and the employees) can benefit from the information contained in the records. The reason the records are transferred (if requested) to the Director of NIOSH is that NIOSH has a vested interest in maintaining records of occupational injuries and illnesses and is in an excellent position to decide how the records can be best used to be of value to the exposed employee, subsequent employees in the field and OSHA. At NIOSH, the records remain confidential as required by 29 CFR 1910.1020(e). Thus, only the employee or his or her representative with the permission of the employee retains access to the medical records transferred to NIOSH.

#### Paragraph (j) Definitions

*Acid-Fast Bacilli (AFB)* means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria. Smears of sputum samples and other clinical specimens may be stained with dyes to detect acid-fast mycobacteria such as *M. tuberculosis*. However, AFB smear tests cannot distinguish one type of mycobacteria from another. Therefore, as noted by CDC, when AFB are seen on a stained smear of sputum or other clinical specimens, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis* (Ex. 4B).

*Accredited Laboratory* for purposes of this standard means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories. Under the medical surveillance provisions of the proposed standard, paragraph (g)(1)(iv) requires that all laboratory tests required by the standard be conducted by an accredited laboratory. This definition makes clear OSHA's intent about the type of laboratory that would be required to conduct these types of tests.

The term *AFB Isolation Room or Area* refers specifically to the rooms or areas where individuals with suspected or confirmed infectious TB are isolated. For purposes of this standard this term includes, but is not limited to, rooms, areas, booths, tents or other enclosures that are maintained at negative pressure relative to adjacent areas in order to control the spread of aerosolized *M. tuberculosis*. Such rooms or areas are

able to contain droplet nuclei through unidirectional airflow into the room (i.e., negative pressure). A definition of negative pressure is presented below and a more detailed explanation can be found in the Summary and Explanation of paragraph (d), *Work Practices and Engineering Controls*.

*Air purifying respirator* means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator. Air purifying respirators remove particular contaminants (e.g., particulates, organic vapors, acid gases) from the ambient air by drawing the air through appropriate filters, cartridges, or canisters.

*Anergy* means the inability of a person to react to skin test antigens (even if the person is infected with the organism(s) tested because of immunosuppression. More specifically, an anergic individual's immune system has become so compromised that it is unable to mount a sufficient reaction to the test organism. Because of their inability to respond immunologically, persons with anergy will have a negative tuberculin skin test even if they are infected with *M. tuberculosis*. Therefore, as noted by the CDC, it may be necessary to consider other epidemiologic factors (e.g., the proportion of other persons with the same level of exposure who have positive tuberculin skin test results and the intensity or duration of exposure to infectious TB patients that the anergic person experienced) when making a determination as to whether that anergic individual has been infected with *M. tuberculosis* (Ex. 4B). As discussed under paragraph (g)(2)(iii), Medical Surveillance, tuberculin skin testing is to include anergy testing when the physician or other licensed health care professional, as appropriate, determines such testing is necessary. Knowing which individuals are anergic will help to determine those situations where information other than skin test status will need to be ascertained and considered in order to assess the likelihood of infection for exposed employees.

*Assistant Secretary* means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative, and is a definition consistent across all OSHA standards.

*BCG (Bacille Calmette-Guerin) vaccine* means a tuberculosis vaccine used in many parts of the world. Because of its variable efficacy and its impact upon tuberculin skin tests (i.e., making skin test interpretation more difficult), routine BCG vaccination is not currently recommended in the

United States (Ex. 7-50). However, many foreign countries still use BCG as part of their tuberculosis control programs, especially for infants (Ex. 7-72). Since individuals vaccinated with BCG may have a tuberculin skin test that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*, it is helpful to know whether an individual has been vaccinated with BCG and when such vaccination occurred. Thus, under the medical surveillance provisions of the proposed standard, the medical history is to include a history of BCG vaccination.

*Cartridge or canister* means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container. With respect to this standard, respirators would be equipped with cartridges or canisters containing particulate filters.

*Clinical laboratory* has been defined for purposes of this standard as a facility or an area of a facility that conducts routine and repetitive operations for the diagnosis of TB, such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing. This definition is meant to apply to laboratories where routine diagnostic tests for TB are conducted as compared to research laboratories where *M. tuberculosis* may be cultured in large volumes or concentrated for research or commercial production. Clinical laboratories may be located within facilities such as hospitals or clinics, or they may be freestanding facilities.

*Confirmed infectious tuberculosis (TB)* means a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR); and the individual is capable of transmitting the disease to another person. The disease state may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei.

As discussed under the definition for AFB, a positive AFB smear indicates only that an individual has an identifiable mycobacterium. The three methods listed here provide positive confirmation of *M. tuberculosis*. In addition, the definition states that the disease state must be capable of being transmitted to another person (i.e., infectious). This provision of the definition is to differentiate this state of the disease from other active forms of TB disease where the individual is not

infectious. For example, an individual may contract active TB disease and become infectious. After adequate drug therapy has been initiated the individual may become noninfectious, at which point he or she cannot transmit the disease to other individuals. However, the individual, while no longer infectious, still has active disease and must continue treatment for several months because living bacilli are still in his or her body. The definition also states that the disease may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei. In most cases, it is the pulmonary or laryngeal forms of infectious TB that present a risk of infection for other individuals. This is due to the fact that tuberculosis bacilli in the pulmonary or laryngeal tracts may be easily dispelled when infectious individuals cough or speak. Other body sites infected with the bacilli, i.e., extrapulmonary TB, do not present an infection hazard in most cases because the bacilli are not capable of being dispelled outside the body. However, in some situations, such as a lesion or an abscess where the infected tissue is exposed, there may be a risk of transmission of disease when certain procedures are performed (e.g., tissue irrigation) that could generate droplet nuclei containing the bacilli.

*Conversion* means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines. Under paragraph (g), the employer is required to provide medical management and follow-up to employees who have converted to positive tuberculin skin test status (e.g., providing preventive therapy, if appropriate, and conducting follow-up investigations of circumstances surrounding the conversion). Since a number of specific actions are required of the employer as a result of a conversion, it is necessary that conversions be correctly identified. An important part of this identification is the interpretation as to whether an employee has a positive skin test response. As such, this definition states that the interpretation of the positive reaction should be based upon current CDC guidelines (Ex. 4B). It is not OSHA's intent to define what should constitute a positive reaction, but rather to assure that such determinations are made using currently accepted public health guidelines.

*Director* means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or

designated representative. Similar to the definition for Assistant Secretary, the definition for Director is consistent across OSHA standards.

*Disposable respirator* means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached. In general, the facepiece of these respirators is constructed from the particular filter media of interest (e.g., particulate filter).

*Exposure incident* for purposes of this standard means an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of all of the applicable exposure control measures required by this section. This definition is limited to those situations involving exposure to an individual with confirmed infectious TB or air originating from an area where a source of aerosolized *M. tuberculosis* is present; it does not include exposure to individuals with suspected infectious TB. OSHA has limited the definition in this way because several provisions in the proposed standard are triggered by the occurrence of an exposure incident. For example, under paragraph (g), *Medical Surveillance*, the employer is required to provide additional tuberculin skin testing to each affected employee and to investigate and document the circumstances surrounding each exposure incident to determine if changes can be instituted to prevent similar occurrences in the future. OSHA believes that it would be burdensome and unnecessary for the employer to conduct follow-up investigations for those occurrences where an employee's exposure is to an individual suspected of having infectious TB but for whom infectious disease is subsequently ruled out.

An example of an exposure incident is an employee entering an AFB isolation room or area occupied by an individual with confirmed infectious TB without the employee wearing appropriate personal respiratory protection equipment. This occurrence would not be defined under the standard as an exposure incident if the individual in the AFB isolation room had only suspected infectious TB. If the individual in AFB isolation room was later confirmed to have infectious TB, the employee entering the isolation room without appropriate respiratory equipment would then be considered to have had an exposure incident and the required medical management and follow-up provisions for an exposure

incident under paragraph (g), *Medical Surveillance*, would be required.

Another example of an exposure incident is a failure of engineering controls, e.g., the ventilation system in an AFB isolation room housing an individual with confirmed infectious TB malfunctioned, negative pressure was lost, and air containing *M. tuberculosis* was dispelled into the hall corridor, exposing unprotected employees. Although OSHA would consider this type of loss of negative pressure in an AFB isolation room to be an exposure incident, the Agency does not intend that each opening of the door to an AFB isolation room be considered an exposure incident, even though some loss of negative pressure may result when the door to an AFB isolation room is opened. As a practical matter, OSHA believes it would be infeasible to consider every instance that a door to an isolation was opened as an exposure incident. In addition, these losses of negative pressure are generally small, if doors are kept open only briefly for purposes of entry and exit and are kept closed at all other times while the room is in operation for TB isolation as required under the Work Practices and Engineering Controls paragraph (d)(5)(vi).

There is a significant difference in the meaning of the terms "exposure incident" and "occupational exposure" as they are used in this standard. This difference is discussed further under the definition of "occupational exposure".

*Filter* means a component used in respirators to remove solid or liquid aerosols from the inspired air. The filter is the medium that captures the aerosol, preventing it from passing through to the respirator wearer.

*Fit factor* is a quantitative measure of the fit of a particular respirator on a particular individual. Fit factor is derived from the ratio of the concentration of a challenge agent (or air pressure) outside of the respirator to the concentration of the test agent (or air pressure) inside the respirator.

*High Efficiency Particulate Air (HEPA) Filter* means a specialized filter that is capable of removing 99.97 percent of particles greater than or equal to 0.3 micrometer in diameter.

*High-hazard procedures* are those procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the induction of coughing or the generation of aerosolized *M. tuberculosis*. Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning,

aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis*. The procedures listed above present a high hazard because they are performed on individuals with suspected or confirmed infectious TB or on specimens or deceased individuals where *M. tuberculosis* may be present. For example, some of the procedures listed above, such as bronchoscopies and pentamidine administration, cause people to cough. For individuals with pulmonary TB, coughing will increase the likelihood that they will generate aerosols with a high concentration of droplet nuclei. In addition, certain autopsy procedures, such as cutting into a lung containing *M. tuberculosis*, and certain laboratory procedures, such as processing infected tissue samples with pressurized freezants, can generate aerosols containing droplet nuclei. In the absence of *M. tuberculosis*, these procedures would not be high-hazard. For example, endotracheal intubation on an individual who does not have suspected or confirmed infectious TB would not be considered a high-hazard procedure.

*M. tuberculosis* means *Mycobacterium tuberculosis*, the scientific name of the bacillus that causes tuberculosis.

*Negative Pressure* means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. Paragraph (d)(5)(i) of Work Practices and Engineering Controls requires that negative pressure be maintained in all AFB isolation rooms or areas, and paragraph (d)(4) requires that all high-hazard procedures be performed in such rooms or areas. Maintaining negative pressure in such rooms or areas helps to assure that droplet nuclei are contained and not spread to other areas of the facility where unprotected employees may be exposed. A further discussion of this principle can be found in the Summary and Explanation of paragraph (d), *Work Practices and Engineering Controls*.

*Negative pressure respirator* means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator. In a negative pressure respirator, the wearer's inhalation creates a drop in pressure inside the facepiece, consequently drawing outside air through the filter and into the respirator.

*Occupational exposure* is one of the key terms upon which the proposed standard rests. It contains the criteria that trigger application of the standard for employees in work settings covered under the scope of the standard as listed in paragraphs (a)(1) through (a)(8) and for employees providing the care and services listed in paragraphs (a)(9) and (a)(10). Although a variety of work settings and several specific types of work are covered within the scope of the standard, it is only employees who have "occupational exposure" in those work settings and who are providing the particular services that must be given the protection mandated by the standard. The exception to this is that an employer covered under paragraph (a), *scope*, must provide medical management and follow-up to other employees who have an exposure incident.

For purposes of this standard, occupational exposure means reasonably anticipated contact, which results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis*. An example of reasonably anticipated contact between an employee and an individual with suspected or confirmed infectious TB would be an admissions clerk working in a homeless shelter. In view of the high incidence of TB among the homeless, it can reasonably be anticipated that an employee screening people for admission into the shelter would have contact with a person with infectious TB during the performance of his or her job duties. Another, more obvious, example would be a bronchoscopist in a hospital that provides care for individuals with suspected or confirmed infectious TB. Others could include some physicians, nurses, paramedics and emergency medical technicians, health aides, prison guards, and intake workers in the facilities listed in paragraph (a) of this section. An example of an employee who would not be reasonably anticipated to have occupational exposure is a worker, in a covered facility, whose duties were limited to working in an area where suspected or confirmed TB patients or clients do not go and where the air would not contain aerosolized *Mycobacterium tuberculosis*. The risk of exposure for this employee is comparable to the exposure potential by the general population.

The term *occupational exposure* is used differently than the term *exposure incident* in the proposed standard. Occupational exposure is used to define

a condition of the employee's work and to identify which employees are affected in a way that can reasonably be anticipated, due to their job duties, to involve potential exposure to aerosolized *M. tuberculosis*, i.e., contact with an individual with suspected or confirmed infectious TB or with air that may contain aerosolized *M. tuberculosis*. The intent of the standard is to prevent exposure to aerosolized *M. tuberculosis*; therefore, certain proactive measures are required by the standard, e.g., training and medical surveillance, when occupational exposure is present. In order to provide these measures, it is necessary to identify which employees may be exposed *before* exposure occurs. The definition of "occupational exposure" is the basis for making this identification.

An *exposure incident*, on the other hand, is a discrete event in which it is known that an employee has had contact with aerosolized *M. tuberculosis*, i.e., with an individual with confirmed infectious TB or air containing aerosolized *M. tuberculosis*. The term "exposure incident" is used to define those occasions when certain reactive measures are required by the standard, such as medical management and follow-up. It is exposure to an individual with confirmed infectious TB that matters, since it is not necessary to take reactive measures after being exposed to an individual with suspected infectious TB if that individual has subsequently been determined not to have infectious TB.

*Physician or Other Licensed Health Care Professional* means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows her or him to independently perform or be delegated to perform some or all of the health care services required by paragraph (g) of this section. Paragraph (g) requires that all medical evaluations and procedures and medical management and follow-up be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA is aware that a variety of health care professionals are licensed by their respective states to legally perform different medical provisions required under this proposed standard. This definition clarifies that it is not OSHA's intent to dictate the specific type of health care professional to perform the activities required by the medical surveillance paragraph. OSHA's intent is merely that these activities be performed by persons who are legally permitted to independently perform or be delegated to perform some or all of the health care services required under

the medical surveillance provisions of the standard. Employers wishing to use the services of a variety of health care providers must be familiar with the licensing laws of their state to ensure that the activities being performed are within the scope of that health care provider's licensure.

*Powered air-purifying respirator (PAPR)* means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone. A PAPR uses a blower to draw ambient air through a filter and provide this filtered air, under pressure, to the facepiece of the wearer.

*Qualitative fit test* means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response. Generally, this assessment of adequacy of respirator fit is made by determining whether an individual wearing the respirator can detect the odor, taste, or irritation of a challenge agent introduced into the vicinity of the wearer's breathing zone.

*Quantitative fit test* means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator. Leakage can be assessed through means such as measuring the concentration of a challenge agent (or air pressure) outside of the respirator versus the concentration of the agent (or air pressure) inside the respirator. The ratio of the two measurements is an index of the leakage of the seal between the respirator facepiece and the wearer's face.

*Research laboratory* is defined as a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories. The purpose of this definition is to distinguish research laboratories from clinical laboratories. Under paragraph (e) of the proposed standard, research laboratories are required to meet additional provisions beyond those required for clinical laboratories (e.g., use of a hazard warning sign incorporating the biohazard symbol when materials containing *M. tuberculosis* are present in the laboratory and use of two sets of self-closing doors for entry into the work area from access corridors). These additional requirements are proposed due to the higher degree of hazard that may be present in research laboratories as a result of the presence of research materials that may contain *M. tuberculosis* in larger volumes and higher concentrations than would

normally be found in diagnostic specimens or cultures in clinical laboratories.

*Respirator* means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants. While the term "respirator" may be used in medical situations to refer to a device that provides breathing assistance to an individual who is experiencing breathing difficulty, this section utilizes this term only in reference to the type of protective device defined above.

*Suspected infectious tuberculosis* means a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. tuberculosis* and to have the signs or symptoms of TB; (2) to have a positive acid-fast bacilli (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

*Suspected infectious TB* is another key term in the proposed standard. The presence of a person with suspected infectious TB triggers and is associated with a number of the provisions required of employers. Applying the criteria associated with suspected infectious TB is the first step in the early identification of individuals with infectious TB and is therefore a key factor in the elimination and minimization of occupational transmission of TB. Therefore, for purposes of implementing the standard it is important that what constitutes "suspected infectious TB" is clear.

The first criterion in identifying an individual as having suspected infectious TB is the presence of TB infection and the signs and symptoms of active TB. Under the second criterion, an individual would be suspected of having infectious TB if that individual had a positive AFB smear. The third criterion is based primarily on observation of an individual. The CDC states that:

\* \* \* A diagnosis of TB may be considered for any patient who has a persistent cough (i.e., a cough lasting for  $\geq 3$  weeks) or other signs or symptoms compatible with active TB (e.g., bloody sputum, night sweats, weight loss, anorexia

or fever). \* \* \* Diagnostic measures for identifying TB should be conducted for patients in whom active TB is being considered. These measures include obtaining a medical history and performing a physical examination, PPD skin test, chest radiograph, and microscopic examination and culture of sputum or other appropriate specimens. (Ex. 4B)

OSHA has relied on the CDC's list of symptoms, but does not agree that employers need only "consider" a TB diagnosis when any of the symptoms appear. The Agency believes that requiring employers merely to consider a TB diagnosis under these circumstances may allow too many individuals with infectious TB to slip through this screen and remain unidentified. In addition, the CDC recommendations do not identify the minimum number of signs or symptoms that should trigger employer concern. The problem with the CDC's approach is that the signs and symptoms are so general that they would be difficult to apply in many of the occupational exposure circumstances covered by the standard. For example, if OSHA required employers to identify each individual with even one of the signs or symptoms of TB as having suspected infectious TB, too many individuals would be likely to be identified, thereby wasting valuable health care resources. For these reasons, OSHA has proposed that employers be required to determine that an individual has suspected infectious TB when the individual has a prolonged cough and at least two of the other signs or symptoms of infectious TB. The Agency believes that requiring the employer to identify individuals as suspect cases when they have only a prolonged cough, which is the primary mode of transmission, and at least 2 other signs or symptoms strikes the appropriate balance between over inclusion and under inclusion, i.e., between considering almost every individual in poor health as a suspect case and missing individuals who should be suspected of having infectious TB. OSHA believes that setting forth these more definitive criteria will meet the needs of the many employers covered by this standard who will not have skilled medical persons making initial determinations about whether or not an individual has suspected infectious TB. Employer who are in a position to make medical determinations are permitted by the standard to rule out infectious TB by determining that a given individual's signs and symptoms are the result of a cause other than TB.

That an employer knows or with reasonable diligence should know that

an individual meets one or more of these criteria means that an employer must utilize the means at his or her disposal to gather relevant information about the individual. For example, the employer may have access to the medical records of the individual or may question an individual who has signs or symptoms of TB in order to obtain information about the individual, such as skin test status, AFB smear status, and so forth. How much questioning the employer might do depends on the work setting. For example, a hospital will have intake procedures that include asking questions, as will most homeless shelters and other fixed work sites. In other work settings, such as the many places in which emergency medical services and home health care are provided to unidentified individuals with infectious TB, the employer's obligation will be to respond when an employee notices signs or symptoms compatible with TB. In many of these instances, it is the training employees receive in identifying individuals with suspected TB that will be the most important factor.

In addition, as noted above, an individual who meets one or more of the above criteria but whose condition has been medically determined to result from a cause other than TB need not be considered to have suspected infectious TB. For example, a physician or other licensed health care professional, as appropriate, could determine that the signs and symptoms exhibited by the individual were the result, for example, of pneumonia and not TB.

*Tight-fitting respirator* means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth while a full facepiece covers the nose, mouth, and eyes.

*Tuberculosis (TB)* means a disease caused by *M. tuberculosis*.

*Tuberculosis infection* means a condition in which living *M. tuberculosis* bacilli are present in the body, without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, the individual may have no symptoms related to the infection and may not be capable of transmitting the disease.

*Tuberculosis disease* is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

*Tuberculin skin test* means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. The method utilizes an intradermal

injection of tuberculin antigen with subsequent measurement of reaction induration. It is also referred to as a PPD skin test.

*Two-step testing* is a baseline skin testing procedure used to differentiate between a boosted skin test reaction and a skin test reaction that signifies a new infection. If the initial skin test is negative, a second skin test is administered 1 to 3 weeks later. If the second skin test is positive, the reaction is probably due to boosting. If the second skin test is negative, the individual is considered to be not infected. A subsequent positive skin test in this individual would thus indicate a new infection. Boosting is discussed in more detail in connection with the Medical Surveillance paragraph.

#### *Paragraph (k) Dates*

As proposed, the final rule would become effective ninety (90) days after publication in the **Federal Register**. This will allow time for public distribution and give employers time to familiarize themselves with the standard. The various provisions have phased-in effective dates.

The employer's initial duty under the standard is the exposure determination and establishment of the written Exposure Control Plan required by paragraph (c) of this section. The plan would need to be completed 30 days after the effective date.

Thirty days later, 60 days after the effective date, paragraphs (h)(3), Information and Training, (g) Medical Surveillance, and (i) Recordkeeping would take effect.

Ninety (90) days after the effective date, the work practice procedures and engineering controls required by paragraph (d) (in work settings other than those noted below), the respiratory protection required by paragraph (f), and the labels and signs required by paragraphs (h) (1) and (2) would take effect. The work practices that are directly related to the engineering controls would have to be implemented as soon as the engineering controls were functional. Finally, the requirements for clinical and research laboratories contained in paragraph (e) would also take effect 90 days after the effective date.

For businesses with fewer than 20 employees, the engineering controls required by paragraph (d) of this section would take effect 270 days after the effective date. As noted above, the work practices directly related to the engineering controls being installed in accordance with paragraph (d) of this section must be implemented as soon as the engineering controls are

implemented. Since engineering controls may necessitate more extensive planning than is required to comply with other provisions of the standard, OSHA is proposing an extended phase-in for the smallest employers.

Since many employers have many of these provisions already in effect through current infection control plans, OSHA believes that these dates provide adequate time for compliance. Nevertheless, OSHA seeks comment on the appropriateness of the dates for compliance with the various provisions of the standard.

### **XI. Public Participation—Notice of Hearing**

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before December 16, 1997, and submitted in quadruplicate to the Docket Officer, Docket No. H-371, Room N2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Comments limited to 10 pages or less also may be transmitted by facsimile to (202) 219-5046, provided the original and three copies are sent to the Docket Officer thereafter.

Written submissions must clearly identify the provisions of the proposal that are being addressed and the position taken with respect to each issue. The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard will be provided at an informal public hearing scheduled to begin at 10:00 A.M. on February 3, 1998, in Washington, DC in the Auditorium of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

#### *Notice of Intention to Appear*

All persons desiring to participate at the hearings must file in quadruplicate a notice of intention to appear postmarked on or before December 16, 1997 addressed to the Docket Officer, Docket No. H-371, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 219-7894. The Notice of Intention to Appear also may be transmitted by facsimile to (202) 219-5046, provided the original and 3 copies of the notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Docket Office, must contain the following information:

- (1) The name, address, and telephone number of each person to appear;
- (2) The hearing site that the party is requesting to attend;
- (3) The capacity in which the person will appear;
- (4) The approximate amount of time requested for the presentation;
- (5) The specific issues that will be addressed;
- (6) A detailed statement of the position that will be taken with respect to each issue addressed;
- (7) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and
- (8) Whether the party wishes to testify on the days set aside to focus on homeless shelters.

#### *Filing of Testimony and Evidence Before Hearings*

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony, including any documentary evidence to be presented at the hearing to the Docket Officer at the above address. This material must be postmarked by December 31, 1997 and will be available for inspection and copying at the OSHA Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper notices of intention to appear will be entitled to ask questions and otherwise participate fully in the proceeding.

#### *Conduct and Nature of Hearings*

The hearings will commence at 10:00 a.m. on February 3, 1998. At that time any procedural matters relating to the proceeding will be resolved.

The nature of an informal hearing is established in the legislative history of

section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15 (a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, the proceeding shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentations that can proceed expeditiously in the absence of rigid procedures that would impede or protract the rulemaking process.

Additionally, since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding, rather than an adjudicative one. The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The hearing will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who makes no recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911 and the prehearing guidelines, including the powers:

- (1) To regulate the course of the proceedings;
- (2) To dispose of procedural requests, objections, and comparable matters;
- (3) To confine the presentation to the matters pertinent to the issues raised;
- (4) To regulate the conduct of those present at the hearing by appropriate means;
- (5) At the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

(6) At the Judges's discretion, to keep the record open for a reasonable, stated time to written information and additional data, views and arguments from any person who has participated in the oral proceeding.

### Information on Homeless Shelter Issues for the Public Hearing

OSHA seeks to gather additional information related to homeless shelters during the written comment period and the public hearing. OSHA recognizes the unique service provided by homeless shelters, yet is also aware that shelters serve a client population that has been identified as possessing a high prevalence of active TB. OSHA is seeking information on all aspects of TB and employee protection against occupational transmission of TB in homeless shelters (e.g., means successfully being used by shelters to achieve early identification of shelter clients with suspected or confirmed infectious TB; successful programs currently being used to protect employees against occupational transmission of TB).

The Agency intends to designate a special session during the Washington, D.C. hearing to focus on the issues surrounding homeless shelters. We encourage hearing participants whose primary testimony will involve homeless shelters to indicate this in their Notice of Intention to Appear; OSHA will attempt to schedule these participants on the day(s) of the hearing set aside to focus on homeless shelters. Other participants whose testimony will not be primarily on homeless shelter issues but who wish to address the topic of homeless shelters will be scheduled another day, but they may enter a separate statement in the record during this period. In any case, participants are free to discuss homeless shelters or any other issue related to this proposed standard whenever they present their testimony.

### Certification of Record and Final Determination After Hearing

Following the close of the posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all testimony and written submissions received as part of the record, and a standard will be issued based on the entire record of the proceeding, including the written comments and data received from the public.

### List of Subjects

#### 29 CFR Part 1910

Health professionals, Occupational safety and health, Reporting and recordkeeping requirements, Tuberculosis.

### XII. Authority and Signature

This document was prepared under the direction of Greg Watchman, Acting Assistant Secretary of Labor, 200 Constitution Avenue, N.W., Washington, D.C., 20210.

It is issued under sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 1-90 (55 FR 9033) and 29 CFR Part 1911.

Signed at Washington, DC, this 15th day of September, 1997.

**Greg Watchman,**

*Acting Assistant Secretary of Labor.*

### XIII. The Proposed Standard

#### General Industry

Part 1910 of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 1910—[AMENDED]

##### Subpart Z—[Amended]

1. The general authority citation for Subpart Z of 29 CFR Part 1910 continues to read as follows and a new citation for § 1910.1035 is added:

**Authority:** Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

\* \* \* \* \*

Section 1910.1035 also issued under 29 U.S.C. 653.

\* \* \* \* \*

2. Section 1910.1035 is added to read as follows:

#### § 1910.1035 Tuberculosis

(a) *Scope.* This section applies to occupational exposure to tuberculosis (TB) occurring:

- (1) In hospitals;
- (2) In long term care facilities for the elderly;
- (3) In correctional facilities and other facilities that house inmates or detainees;
- (4) In hospices;
- (5) In shelters for the homeless;
- (6) In facilities that offer treatment for drug abuse;
- (7) In facilities where high-hazard procedures (as defined by this section) are performed;

(8) In laboratories that handle specimens that may contain *M. tuberculosis*, or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of *M. tuberculosis*;

**Note to paragraph (a)(8):** Occupational exposure incurred in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section by temporary or contract employees or by personnel who service or repair air systems or equipment or who renovate, repair, or maintain areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is covered by this section.

(9) During the provision of social work, social welfare services, teaching, law enforcement or legal services if the services are provided in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section, or in residences, to individuals who are in AFB isolation or are segregated or otherwise confined due to having suspected or confirmed infectious TB.

(10) During the provision of emergency medical services, home health care and home-based hospice care.

(b) *Application.* An employer covered under paragraph (a) of this section, Scope (other than the operator of a laboratory), may choose to comply only with the provisions of appendix A to this section if the Exposure Control Plan demonstrates that his or her facility or work setting: (1) Does not admit or provide medical services to individuals with suspected or confirmed infectious TB; and

(2) Has had no case of confirmed infectious TB in the past 12 months; and

(3) Is located in a county that, in the past 2 years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year.

(c) *Exposure control*—(1) *Exposure determination.* (i) Each employer who has any employee with occupational exposure shall prepare an exposure determination that contains the following:

(A) A list of the job classifications in which all employees have occupational exposure; *and*

(B) A list of the job classifications in which some employees have occupational exposure, and a list of all tasks and procedures (or groups of closely related tasks and procedures) that these employees perform and that involve occupational exposure.

(ii) The exposure determination shall be made without regard to the use of respiratory protection.

(2) *Exposure Control Plan.* (i) Each employer who has any employee with occupational exposure shall establish a written Exposure Control Plan that must include:

(A) The exposure determination required by paragraph (c)(1) of this section;

(B) Procedures for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions; and

(C) Procedures for reporting an exposure incident, including procedures specifying the individual to whom the incident is to be reported, and procedures for evaluating the circumstances surrounding the exposure incident.

(ii) Each employer who transfers individuals with suspected or confirmed infectious TB to a facility with AFB isolation capabilities shall include in the Exposure Control Plan procedures for prompt identification, masking or segregation, and transfer of such individuals.

**Note to paragraph (c)(2)(ii):** An employer's duties regarding transfer will vary with the type of facility the employer operates and the work performed by his or her employees. For example, the transfer responsibilities of hospitals, long-term care facilities for the elderly, correctional facilities, and hospices may include contacting the receiving facility, providing transport, and taking other steps to ensure that the individual with suspected or confirmed infectious TB reaches the receiving facility. By contrast, the responsibilities of facilities that do not maintain custody over individuals, such as homeless shelters or facilities that offer treatment for drug abuse, might only include providing information about the receiving facility, contacting the facility, and providing directions to the facility.

(iii) Each employer in whose facility individuals with suspected or confirmed infectious TB are admitted or provided medical services shall include each of the following provisions in the Exposure Control Plan:

(A) Procedures for prompt identification of individuals with suspected or confirmed infectious TB;

(B) Procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB, including:

(1) Minimizing the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation

room or area (e.g., in an emergency room);

(2) Minimizing employee exposure in AFB isolation rooms or areas by combining tasks to limit the number of entries into the room or area and by minimizing the number of employees who must enter and minimizing the time they spend in the room or area;

(3) Delaying elective transport or relocation within the facility of an individual with suspected or confirmed infectious TB. Procedures are to be established to assure that, to the extent feasible, services and procedures for individuals with suspected or confirmed infectious TB are brought into or conducted in an AFB isolation room or area;

(4) Using properly-fitted masks (e.g., surgical masks, valveless respirators) on individuals with suspected or confirmed infectious TB or transporting such individuals in portable containment engineering controls when relocation or transport outside of AFB isolation rooms or areas is unavoidable. Procedures are to be established to assure that the individual is returned to an AFB isolation room or area as soon as is practical after completion of the service or procedure;

(5) Delaying elective high-hazard procedures or surgery until an individual with suspected or confirmed infectious TB is determined to be noninfectious;

(C) A list of all high-hazard procedures, if any, performed in the work setting; and

(D) A schedule for inspection, maintenance, and performance monitoring of engineering controls (see appendix E to this section).

(iv) Each employer who operates a laboratory shall include in the Exposure Control Plan a determination from the director of the laboratory as to whether the facility should operate at Biosafety Level 2 or 3 containment according to current CDC recommendations (CDC/NIH Biosafety in Microbiological and Biomedical Laboratories). The laboratory director shall determine and document the need for:

(A) Controlled access;

(B) Anterooms;

(C) Sealed windows;

(D) Directional airflow;

(E) Measures to prevent recirculation of laboratory exhaust air;

(F) Filtration of exhaust air before discharge outside; and

(G) Thimble exhaust connections for biological safety cabinets.

(v) Each employer who provides home health care or home-based hospice care shall include in the Exposure Control Plan procedures for

prompt identification of individuals with suspected or confirmed infectious TB and procedures for minimizing employee exposure to such individuals; a list of the high-hazard procedures, if any, performed in the work setting; and procedures for delaying elective high-hazard procedures or surgery until the individual is noninfectious.

(vi) Each employer who claims reduced responsibilities related to paragraph (b), Application, or paragraph (g)(3)(iii)(D), Medical Surveillance, of this section shall document in the Exposure Control Plan the number of individuals with confirmed infectious tuberculosis encountered in the work setting in the past 12 months.

(vii) The Exposure Control Plan shall be:

(A) Accessible to employees in accordance with 29 CFR 1910.20(e);

(B) Reviewed at least annually and updated whenever necessary to reflect new or modified tasks, procedures, or engineering controls that affect occupational exposure and to reflect new or revised employee job classifications with occupational exposure; and

(C) Made available for examination and copying to the Assistant Secretary and/or the Director upon request.

(d) *Work Practices and Engineering Controls.* (1) Work practices and engineering controls shall be used to eliminate or minimize employee exposures to *M. tuberculosis*.

(2) The work practices in the Exposure Control Plan shall be implemented.

(3) Individuals with suspected or confirmed infectious TB shall be identified, and except in settings where home health care or home-based hospice care is being provided, shall be:

(i) Masked or segregated in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an AFB isolation room or area can be accomplished; and

(ii) Placed in an AFB isolation room or area or transferred to a facility with AFB isolation rooms or areas within 5 hours from the time of identification, or temporarily placed in AFB isolation within 5 hours until placement or transfer can be accomplished as soon as possible thereafter.

(4) High-hazard procedures shall be conducted in an AFB isolation room or area.

(5) Engineering controls shall be used in facilities that admit or provide medical services or AFB isolation to individuals with suspected or confirmed infectious TB except in

settings where home health care or home-based hospice care is being provided.

(i) Negative pressure shall be maintained in AFB isolation rooms or areas.

(ii) Negative pressure shall be qualitatively demonstrated (e.g., by smoke trails) daily while a room or area is in use for TB isolation (see appendix G to this section).

(iii) Engineering controls shall be maintained, and inspected and performance monitored for filter loading and leakage every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness (see appendix E to this section).

(iv) Air from AFB isolation rooms or areas shall be exhausted directly outside, away from intake vents, employees, and the general public. Air that cannot be exhausted in such a manner or must be recirculated must pass through HEPA filters before discharge or recirculation.

(v) Ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge.

(vi) Doors and windows of AFB isolation rooms or areas shall be kept closed while in use for TB isolation, except when doors are opened for entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure.

(vii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection (see appendix C to this section).

(6) The employer shall provide information about the TB hazard to any contractor who provides temporary or contract employees who may incur occupational exposure so that the contractor can institute precautions to protect his or her employees.

(e) *Clinical and Research Laboratories.* (1) This paragraph applies to clinical and research laboratories that engage in the culture, production, concentration, experimentation, or manipulation of *M. tuberculosis*. The requirements in this paragraph apply in addition to the other requirements of the standard.

(2) Clinical and research laboratories shall meet the following criteria:

(i) Standard microbiological practices.

(A) Procedures shall be performed in a manner that minimizes the creation of aerosols.

(B) Mouth pipetting shall be prohibited.

(C) Work surfaces and laboratory equipment shall be decontaminated at the end of each shift and after any spill of viable material.

(D) Cultures, stocks and other wastes contaminated with *M. tuberculosis* shall be decontaminated before disposal by a decontamination method, such as autoclaving, known to effectively destroy *M. tuberculosis*. Materials to be decontaminated outside of the immediate laboratory shall be placed in a durable, leakproof container, closed and sealed for transport from the laboratory and labeled or color-coded in accordance with paragraph (h)(1)(ii) of this section.

(ii) *Special practices.* (A) Access to the laboratory shall be limited by the laboratory director when work with *M. tuberculosis* is in progress.

(B) A biosafety manual that includes procedures for spill management shall be adopted. The employer shall review the manual as necessary and at least annually. The employer shall update the biosafety manual as necessary to reflect changes in the work setting. Employees shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(C) Cultures, tissues, or specimens of body fluids contaminated with *M. tuberculosis* shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(D) All spills shall be immediately contained and cleaned up by employees who are properly trained and equipped to work with potentially concentrated *M. tuberculosis*. A spill or accident that results in an exposure incident shall be reported immediately to the laboratory director or other designated person.

(E) When materials containing or animals infected with *M. tuberculosis* are present in the laboratory or containment module, a hazard warning sign, in accordance with paragraph (h)(2)(iv), incorporating the universal biohazard symbol, shall be posted on all laboratory and animal room access doors.

(iii) *Containment equipment.* (A) Certified biological safety cabinets (Class 2) shall be used whenever procedures with a potential for generating aerosols of *M. tuberculosis* are conducted or whenever high concentrations or large volumes of *M. tuberculosis* are used. Such materials may be centrifuged in the open

laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened in a biological safety cabinet.

(B) Biological safety cabinets shall be certified when installed, annually thereafter, whenever they are moved, and whenever filters are changed.

(iv) Laboratory facilities. A method for decontamination of wastes contaminated with *M. tuberculosis* (e.g., autoclave, chemical disinfection, incinerator, or other decontamination system known to effectively destroy *M. tuberculosis*) shall be available within or as near as feasible to the work area.

(3) Research laboratories shall meet the following additional criteria:

(i) *Special practices.* (A) Laboratory doors shall be kept closed when work involving *M. tuberculosis* is in progress.

(B) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established so that only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(C) Respiratory protection shall be worn when aerosols cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(ii) *Containment equipment.* Certified biological safety cabinets (Class 2 or 3) or appropriate combinations of personal protection or physical containment devices, such as respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for manipulations of cultures and those clinical or environmental materials that may be a source of aerosols containing *M. tuberculosis*; aerosol challenge of animals with *M. tuberculosis*; harvesting of tissues or fluids from animals infected with *M. tuberculosis*; or the necropsy of animals infected with *M. tuberculosis*.

(iii) *Laboratory facilities.* (A) The laboratory shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors shall be required for entry into the work area from access corridors or other contiguous areas.

(B) Windows in the laboratory shall be closed and sealed.

(C) A ducted exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air from "clean" areas into the laboratory toward "contaminated" areas. The employer shall verify the proper direction of the airflow (i.e., into

the work area) at least every six months. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes.

(D) The high efficiency particulate air (HEPA)-filtered exhaust air from Class 2 or Class 3 biological safety cabinets shall be discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class 2 or 3 biological safety cabinets is to be discharged to the outside through the building exhaust air system, it shall be connected to this system in a manner (e.g., thimble units) that avoids any interference with the air balance of the cabinets or building exhaust system.

(E) Continuous flow centrifuges or other equipment that may produce aerosols shall be contained in devices that exhaust air through HEPA filters before discharge into the laboratory.

(f) *Respiratory Protection*—(1)

*General.* (i) Each employer shall provide a respirator to each employee who:

(A) Enters an AFB isolation room or area in use for TB isolation;

(B) Is present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked;

(C) Transports an individual with suspected or confirmed infectious TB in an enclosed vehicle (e.g., ambulance, helicopter) or who transports an individual with suspected or confirmed infectious TB within the facility when that individual is not masked;

(D) Repairs, replaces, or maintains air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis*;

(E) Is working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined (e.g., while awaiting transfer); or

(F) Is working in a residence where an individual with suspected or confirmed infectious TB is known to be present.

(ii) Each employer who operates a research laboratory shall provide a respirator to each employee who is present when aerosols of *M. tuberculosis* cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(iii) The employer shall provide the respirator at no cost to the employee and shall assure that the employee uses the respirator in accordance with the requirements of this section.

(iv) The employer shall assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks set forth in

paragraphs (f)(1)(i) and (f)(1)(ii) of this section and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

(2) *Respiratory Protection Program.* (i) Each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in paragraph (f)(1) of this section shall establish and implement a written respiratory protection program that assures respirators are properly selected, fitted, used, and maintained. The program shall include the following elements:

(A) Procedures for selecting the appropriate respirators for use in the work setting;

(B) A determination of each employee's ability to wear a respirator, as required under paragraph (g)(3)(ii) of this section, Medical Surveillance, for each employee required to wear a respirator;

(C) Procedures for the proper use of respirators;

(D) Fit testing procedures for tight-fitting respirators;

(E) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, or otherwise maintaining respirators;

(F) Training of employees to assure the proper use and maintenance of the respirator, as required under paragraph (h) of this section, Communication of Hazards and Training; and

(G) Procedures for periodically evaluating the effectiveness of the program.

(ii) The employer shall designate a person qualified by appropriate training or experience to be responsible for the administration of the respiratory protection program and for conducting the periodic evaluations of its effectiveness.

(iii) The employer shall review and update the written program as necessary to reflect current workplace conditions and respirator use.

(iv) The employer shall, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. A copy of the program shall be submitted to the Assistant Secretary and/or the Director, if requested.

(3) *Respirator Selection.* (i) The employer shall select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators shall be capable of being:

(A) Qualitatively or quantitatively fit tested in a reliable way to verify a face-seal leakage of no more than 10%; and

(B) Fit checked by the employee each time the respirator is donned.

(ii) The employer shall select a respirator that will function effectively in the conditions of the work setting. In addition to meeting the criteria in paragraph (f)(3)(i) of this section, the respirator shall be, at a minimum, either a HEPA respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11, or an N95 respirator certified by NIOSH under the provisions of 42 CFR part 84.

(4) *Respirator Use.* (i) The employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any condition that prevents such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or if facial hair interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal.

(ii) The employer shall assure that each employee who wears corrective glasses or goggles wears them in a manner that does not interfere with the seal of the facepiece to the face of the wearer.

(iii) Disposable respirators shall be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use.

(iv) The employer shall assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. The procedures in appendix B to this section or other procedures recommended by the respirator manufacturer that provide protection equivalent to that provided by the procedures in appendix B shall be used.

(v) Respirators shall be immediately repaired, or discarded and replaced, when they are no longer in proper working condition.

(vi) The employer shall permit each employee to leave the respirator use area as soon as practical to:

(A) Change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or

(B) Wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use.

(vii) Each employee required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section.

(viii) No employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be performed in accordance with paragraph (g)(5)(iii) of this section.

(5) *Fit Testing.* (i) The employer shall perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in appendix B to this section.

(ii) The employer shall assure that each employee who must wear a tight-fitting respirator passes a fit test:

(A) At the time of initial fitting;

(B) Whenever changes occur in the employee's facial characteristics which affect the fit of the respirator;

(C) Whenever a different size or make of respirator is used; and

(D) At least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section indicates that the annual fit test is not necessary.

(iii) When quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting half-mask respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber.

(6) *Maintenance and care of reusable and powered air purifying respirators.*

(i) Respirators shall be cleaned and disinfected using the cleaning procedures recommended by the manufacturer at the following intervals:

(A) As necessary for respirators issued for the exclusive use of an employee; and

(B) After each use for respirators issued to more than one employee.

(ii) Respirators shall be inspected before each use and during cleaning after each use;

(iii) Respirator inspections shall include:

(A) A check of respirator function, tightness of connections and the

condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and

(B) A check of the rubber or elastomer parts for pliability and signs of deterioration.

(iv) Respirators that fail to pass inspection shall be removed from service and shall be repaired or adjusted in accordance with the following:

(A) Repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer, and conducted by persons appropriately trained to perform such operations;

(B) Only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and

(C) Reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for adjustment or repair.

(v) Respirators shall be stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals and prevents deformation of the facepiece or exhalation valve.

(7) *Identification of filters, cartridges, and canisters.* (i) Filters, cartridges, and canisters used in the workplace shall be properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service.

(ii) The NIOSH approval label on a filter, cartridge, or canister shall not be intentionally removed, obscured, or defaced while it is in service in the workplace.

(8) *Respiratory protection program evaluation.* The employer shall review the overall respiratory protection program at least annually, and shall conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The review of the program shall include an assessment of each element required under paragraph (f)(2) of this section.

(g) *Medical Surveillance—(1) General.* (i) Each employer who has any employee with occupational exposure shall provide the employee with medical surveillance as described in this paragraph.

(ii) Each employer covered under paragraph (a), *Scope*, of this section shall provide information about the signs and symptoms of pulmonary TB, a medical history, a physical examination, TB skin testing, medical

management and follow-up and, if indicated, other related tests and procedures, and medical removal protection if the employee develops infectious TB, to any of his or her employees who have an exposure incident while working in a covered work setting, even if such employee is not categorized as having occupational exposure.

(iii) Medical surveillance provisions, including examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:

(A) Provided at no cost to the employee;

(B) Provided at a reasonable time and place for the employee;

(C) Performed by or under the supervision of a physician or other licensed health care professional, as appropriate; and

(D) Provided according to recommendations of CDC current at the time these evaluations and procedures take place, except as specified by this paragraph (g).

(iv) Laboratory tests shall be conducted by an accredited laboratory.

(2) *Explanation of Terms.* This paragraph explains the terms used in paragraph (g).

(i) *Medical history* emphasizes the pulmonary system, and includes previous exposure to *M. tuberculosis*, BCG vaccination, TB skin test results, TB disease, prior and current preventive or therapeutic treatment, current signs or symptoms of active TB disease, and factors affecting immunocompetence;

(ii) *Physical examination* emphasizes the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence;

(iii) *TB skin testing*, includes energy testing if indicated, and is only for employees whose TB skin test status is not known to be positive. An initial 2-step protocol is to be used for each employee who has not been previously skin tested and/or for whom a negative test cannot be documented within the past 12 months. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be utilized to fulfill the skin testing portion of this requirement. Periodic retesting shall be performed in accordance with paragraph (g)(3) of this section.

(iv) "Determination of the employee's ability to wear a respirator" is a face-to-face assessment of the health factors affecting respirator use and the need for the annual fit test.

**Note to paragraph (g)(2)(iv):** A determination of the need for the annual fit

test may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, for example, when a different size or make of respirator is used.

(v) "Medical management and follow-up" include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease.

(vi) *Other related tests and procedures* include those associated with TB infection and disease and determined to be necessary by the physician or other licensed health care professional, as appropriate.

(vii) Medical Removal Protection is the maintenance of earnings, seniority and other benefits specified in paragraph (g)(5) of this section for an employee who has confirmed or suspected infectious TB or is unable to wear a respirator.

(3) *Application.* (i) Each employee with occupational exposure shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A medical history and TB skin testing, and, if indicated, a physical examination and other related tests and procedures;

**Note to paragraph (g)(3)(i)(A):** If an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has the documented results of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The date(s) of the previous medical examination and skin test shall be used to determine the date(s) of the employee's next medical examination and skin test but in no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months.

(B) When the employee has signs or symptoms of TB, either observed or self-reported: A medical history, a physical examination, TB skin testing, medical management and follow-up, and, if indicated, other related tests and procedures;

(C) When an employee undergoes an exposure incident: A medical history, TB skin testing as soon as feasible (unless there is documented negative TB skin testing within the past 3 months), and if the result is negative, another skin test 3 months later, medical management and follow-up and, if indicated, a physical examination and other related tests and procedures;

(D) When the employee has a TB skin test conversion: A medical history, a physical examination, medical

management and follow-up, and, if indicated, other related tests;

(E) Within 30 days of the termination of employment: A TB skin test; and

(F) At any other time the physician or other licensed health care professional, as appropriate, deems it necessary: Any or all the provisions of paragraph (g).

(ii) Each employee who must wear a respirator shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A determination of the employee's ability to wear a respirator; and

(B) When the wearer experiences unusual difficulty while being fitted or while using a respirator: A determination of the employee's ability to wear a respirator, including relevant components of a medical history, and, if indicated, a physical examination and other related tests and procedures.

(iii) An employee with negative TB skin test status shall be provided with a TB skin test every 6 months if the employee in the course of his or her duties:

(A) Enters an AFB isolation room or area;

(B) Performs or is present during the performance of high-hazard procedures;

(C) Transports or is present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle; or

(D) Works in an intake area where early identification procedures are performed (e.g., emergency departments, admitting areas) in facilities where six (6) or more individuals with confirmed infectious TB have been encountered in the past twelve months.

(4) *Additional Requirements.* (i) The employer shall assure that when the physician or other licensed health care professional, as appropriate, determines that an employee has suspected or confirmed infectious TB, the physician or other licensed health care professional, as appropriate, shall notify the employer and the employee as soon as feasible.

(ii) When the employer first identifies an individual with confirmed infectious TB, the employer shall notify each employee who has had an exposure incident involving that individual of his or her exposure to confirmed TB; and

(iii) When an exposure incident results in a TB skin test conversion, the employer shall assure that a determination is made of the drug susceptibility of the *M. tuberculosis* isolate from the source, unless the

employer can demonstrate that such a determination is not feasible.

(iv) When an exposure incident or a TB skin test conversion occurs, the employer shall investigate and document the circumstances surrounding the exposure incident or conversion (e.g. failure of engineering controls or work practices and events leading to the exposure incident) to determine if changes can be instituted to prevent similar occurrences in the future.

(5) *Medical Removal Protection.* (i) Each employee with suspected or confirmed infectious TB shall be removed from the workplace until determined to be noninfectious.

(ii) For each employee who is removed from the workplace under paragraph (g)(5)(i) of this section, the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status, as if the employee had not been removed from the employee's job or otherwise medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first.

(iii) For each employee who is removed from his or her job under paragraph (f)(4)(viii), Respiratory Protection, of this section the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required. The employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits. If there is no such work available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for a maximum of 18 months, whichever comes first.

(iv) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(6) *Information Provided to Physician or Other Licensed Health Care Professionals.* (i) Each employer shall assure that all physicians or other licensed health care professionals responsible for making determinations and performing procedures as part of the medical surveillance program are

provided a copy of this regulation and, for those employees required to wear respirators under this section, information regarding the type of respiratory protection used, a description of the work effort required, any special environmental conditions (e.g., heat, confined space entry), additional requirements for protective clothing and equipment, and the duration and frequency of usage of the respirator.

(ii) Each employer shall assure that the physician or other licensed health care professional, as appropriate, who evaluates an employee after an exposure incident is provided the following information:

(A) A description of the exposed employee's duties as they relate to the exposure incident;

(B) Circumstances under which the exposure incident occurred;

(C) Any diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure which could assist in the medical management of the employee; and

(D) All of the employee's medical records relevant to the management of the employee, including tuberculin skin testing results.

(7) *Written Opinion.* (i) Each employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section.

(ii) The written opinion shall be limited to the following information:

(A) The employee's TB skin test status;

(B) The employee's infectivity status;

(C) A statement that the employee has been informed of the results of the medical evaluation;

(D) A statement that the employee has been told about any medical conditions resulting from exposure to TB that require further evaluation or treatment;

(E) Recommendations for medical removal or work restrictions and the physician's or other licensed health care professional's opinion regarding the employee's ability to wear a respirator.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(h) *Communication of Hazards and Training—(1) Labels.* (i) Air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be labeled "Contaminated Air—Respiratory Protection Required." The label shall be placed at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and

discharge outlets of non-HEPA filtered direct discharge systems.

(ii) Clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory shall be labeled with the biohazard symbol or placed in a red container(s).

(2) *Signs.* (i) Signs shall be posted at the entrances to:

(A) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB;

(B) Areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB; and

(C) Clinical and research laboratories where *M. tuberculosis* is present.

(ii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9% (see Appendix C to this section).

(iii) Signs for AFB isolation rooms or areas, except as required in paragraph (h)(2)(iv) of this section, shall be readily observable and shall bear the following legend with symbol and text in white on a red background:

BILLING CODE 4510-26-P



BILLING CODE 4510-26-C

**No Admittance Without Wearing a Type N95 or More Protective Respirator**

**Note to paragraph (h)(2)(ii):** Employers may include additional information on signs provided it does not interfere with conveyance of this message.

(iv) Signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* shall include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation *Mycobacterium tuberculosis*, and special requirements for entering the laboratory or autopsy room.

(3) *Information and Training.* (i) Each employer shall assure that each employee with occupational exposure participates in a training program, which must be provided at no cost to the employee and be made available at a reasonable time and place.

(ii) Training shall be provided as follows:

(A) Before initial assignment to tasks where occupational exposure may occur;

(B) Within 60 days after the effective date of the standard; and

(C) At least annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii) of this section. The employer must provide re-training to the employee in any topic(s) in which specific knowledge and skills cannot be demonstrated.

**Note to paragraph (h)(3)(ii):** Training in the general topics under paragraph (h)(3)(vii) of this section which has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics under paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h).

(iii) For employees who have received training on TB in the year preceding the effective date of the standard, only training with respect to the provisions of the standard that were not included in such training need be provided. The annual retraining shall be conducted within one year from the date of the training that occurred before the effective date of the standard.

(iv) Annual training for each employee shall be provided within one calendar year of the employee's previous training.

(v) The employer shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new or modified exposures.

(vi) Material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.

(vii) The training program shall include an explanation of:

(A) The contents of this standard and the location of an accessible copy of the regulatory text of this standard;

(B) The general epidemiology of TB, including Multidrug-Resistant TB (MDR-TB), and the potential for exposure within the facility; the signs and symptoms of TB, including the difference between tuberculosis

infection and tuberculosis disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase the employee's risk of developing TB disease if infected (e.g., HIV infection, prolonged corticosteroid therapy, other immunocompromising conditions);

(C) The employer's exposure control plan and respiratory protection program and the means by which the employee can review the written plans;

(D) The tasks and other activities that may involve exposure to *M. tuberculosis*;

(E) The use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, respiratory protection, and site-specific control measures;

(F) Why a respirator is necessary, and the basis of selection of the respirators used, the types of respirators used, upkeep and storage of the respirators used, and their location and proper use, including procedures for inspection, donning and removal, checking the fit and seals, and wearing the respirator. This instruction shall allow sufficient practice to enable the employee to become thoroughly familiar with and effective in performing these tasks;

(G) The employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program;

(H) The procedures to follow if an exposure incident occurs, including the method of reporting the incident and the medical management and follow-up that the employer is required to provide, and the benefits and risks of prophylaxis; and

(I) The procedures to follow if the employee develops signs or symptoms of TB disease.

(viii) The person(s) conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) The employer shall provide employees with an opportunity for interactive questions and answers with the person conducting the training session.

(i) *Recordkeeping*—(1) *Medical Records*. (i) Each employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name, social security number, and job classification of the employee;

(B) A copy of all results of examinations; medical testing, including the employee's tuberculin skin test status; and follow-up procedures;

(C) The employer's copy of the physician's or other licensed health care professional's written opinion; and

(D) A copy of the information provided to the physician or other licensed health care professional.

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (i) are:

(A) Kept confidential; and

(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace, except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (i)(1) for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020. The medical records of employees who have worked for less than one year for the employer need not be retained beyond the term of employment if they are provided to the employee upon termination of employment.

(2) *OSHA Illness and Injury Records*. The employer shall record TB infection or disease in accordance with 29 CFR 1904 and 29 CFR 1960, as applicable.

(3) *Training Records*. (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The name and job classification of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(4) *Engineering Control Maintenance and Monitoring Records*. (i) Engineering control maintenance records shall include the following information:

(A) Date;

(B) Equipment identification;

(C) Task performed; and

(D) Sign-off.

(ii) Performance monitoring records shall include the following information:

(A) Date and time;

(B) Location;

(C) Parameter measured, including units when appropriate;

(D) Results of monitoring; and

(E) Sign-off.

(iii) Engineering control maintenance and monitoring records shall be maintained for three years.

(5) *Availability*. (i) Employee medical records required by paragraph (i)(1), Recordkeeping, of this section shall be provided upon request for the examination and copying to the subject employee, to anyone having the written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020. OSHA Illness and Injury Records shall be accessible under the provisions of 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) Employee training records required by paragraph (i)(3), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, to their representatives, to the Director, and to the Assistant Secretary.

(iii) Engineering control maintenance and monitoring records required by paragraph (i)(4), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, their representatives, to the Director, and to the Assistant Secretary.

(6) *Transfer of Records*. (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h) and 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least three months before their disposal and transmit them to the Director, if required by the Director to do so, within the three month period.

(j) *Definitions*. For the purposes of this section, the following shall apply:

*Acid-fast bacilli (AFB)* means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria.

*Accredited laboratory* means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

*Air-purifying respirator* means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator.

*AFB isolation room or area* includes, but is not limited to, rooms, areas, booths, tents, or other enclosures that are maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis*.

*Anergy* means the inability of a person to react to skin test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

*Assistant Secretary* means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

*BCG (Bacille Calmette-Guerin) vaccine* is a tuberculosis vaccine.

*Canister* or *cartridge* means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container.

*Clinical laboratory* is a laboratory or area of a facility that conducts routine and repetitive operations for the diagnosis of TB such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing.

*Confirmed infectious tuberculosis* is a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR). The disease state must be capable of being transmitted to another individual (e.g., pulmonary or laryngeal TB or extrapulmonary TB where the infected tissue is exposed and could generate droplet nuclei).

*Conversion* means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines.

*Director* means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

*Disposable respirator* means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached.

*Exposure incident* means an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of applicable exposure control measures required by this section.

*Filter* means a component used in respirators to remove solid or liquid aerosols from the inspired air.

*Fit factor* means a quantitative measure of the fit of a particular respirator on a particular individual.

*High efficiency particulate air (HEPA) filter* means a specialized filter that is capable of removing 99.97% of particles

greater than or equal to 0.3 micrometer in diameter.

*High hazard procedures* are procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the reasonably anticipated generation of aerosolized *M. tuberculosis*. Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis*.

*M. tuberculosis* means *Mycobacterium tuberculosis*, the scientific name of the bacillus that causes tuberculosis.

*Negative pressure* means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas.

*Negative pressure respirator* means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

*Occupational exposure* means reasonably anticipated contact, that results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis*.

*Physician or other licensed health care professional* means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (g) of this section.

*Powered air-purifying respirator (PAPR)* means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone.

*Qualitative fit test* means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response to a challenge agent.

*Quantitative fit test* means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

*Research laboratory* is a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification

and typing activities common to clinical laboratories.

*Respirator* means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants.

*Suspected infectious tuberculosis* means a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB:

- (1) To be infected with *M. tuberculosis* and to have the signs or symptoms of TB;
- (2) To have a positive acid-fast bacilli (AFB) smear; or
- (3) To have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

*Tight-fitting facepiece* means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth; a full facepiece covers the nose, mouth, and eyes.

*Tuberculosis (TB)* means a disease caused by *M. tuberculosis*.

*Tuberculosis infection* means a condition in which living *M. tuberculosis* bacilli are present in the body without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, he or she may have no symptoms related to the infection and may not be capable of transmitting the disease.

*Tuberculosis disease* is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

*Tuberculin skin test* means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of the reaction induration. It is also referred to as a PPD skin test.

*Two-step testing* is a baseline skin testing procedure used to identify a boosted skin test reaction from that of a new infection. The procedure involves placing a second skin test 1 to 3 weeks after an initial negative test. A positive reaction on the second test indicates a boosted reaction.

(k) *Dates.*—(1) *Effective Date.* The standard shall become effective on [insert date 90 days after publication of final rule in the **Federal Register**].

(2) *Start-up dates.* (i) *Exposure control.* The exposure control provisions required by paragraph (c) of this section shall take effect on [insert date 30 days after effective date of final rule].

(ii) The *Information and Training* provisions required under paragraph (h)(3), the *Medical surveillance* provisions required by paragraph (g), and the *Recordkeeping* provisions required by paragraph (i) of this section shall take effect on [insert date 60 days after effective date of final rule].

(iii) *Work practices and Engineering controls.* The work practice and engineering control provisions required by paragraph (d) of this section shall take effect on [insert date 90 days after effective date of final rule]. For businesses with fewer than 20 employees, engineering controls required by paragraph (d) of this section shall take effect [insert 270 days after effective date of final rule]. Work practice controls that are directly related to engineering controls being installed in accordance with this paragraph shall be implemented as soon as those engineering controls are implemented.

(iv) *Respiratory protection.* Respiratory protection provisions required by paragraph (f) of this section shall take effect on [insert date 90 days after effective date of final rule].

(v) *Labels and signs.* The labels and signs provisions required by paragraphs (h)(1) and (h)(2) of this section shall take effect on [insert date 90 days after effective date of final rule].

(vi) *Clinical and research laboratories.* The additional requirements for Clinical and Research Laboratories contained in paragraphs (e)(1) through (e)(3) shall take effect on [insert date 90 days after effective date of final rule].

#### **Appendix A to § 1910.1035—Provisions for Employers Claiming Reduced Responsibilities Under Paragraph (b), Application (Mandatory)**

##### *(c) Exposure Control*

Paragraph (c)(1)(i & ii) Exposure Determination

(c)(2)(i) Written Exposure Control Plan with the following elements:

(c)(2)(i)(A) The exposure determination

(c)(2)(i)(B) Procedures for providing information to employees about individuals identified with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*

(c)(2)(i)(C) Procedures for reporting an exposure incident

(c)(2)(ii) Procedures for identifying, masking or segregating and transferring individuals with suspected or confirmed infectious TB

(c)(2)(vi) Documentation of the number of individuals with confirmed infectious TB encountered in the past 12 months

(c)(2)(vii) (A–C) Accessible exposure control plan, reviewed annually and updated as necessary, and made available to the Assistant Secretary and Director

##### *(d) Work Practice Procedures and Engineering Controls*

(d)(1) Use of work practices to eliminate or minimize employee exposure

(d)(2) Implementation of the work practice procedures in the exposure control plan

(d)(3)(i) Identification and masking or segregating of individuals with suspected or confirmed infectious TB

(d)(3)(ii) Temporary isolation of individuals who cannot be transferred within 5 hours

(d)(5)(i–vii) Engineering controls if temporary isolation is used

(d)(6) Provide information about TB hazards to temporary or personnel who may incur occupational exposure

##### *(g) Medical Surveillance*

(g)(1)(i–iv) Medical surveillance program for each employee with occupational exposure or who has an exposure incident in one of the covered work settings, at no cost, at a reasonable time, by a physician or other licensed health care professional, according to current recommendations of the CDC and with laboratory tests conducted by an accredited laboratory

(g)(2)(i, ii, iii, v, vi & vii) Explanation of terms: Medical history, Physical examination, tuberculin skin testing, medical management and follow-up, medical removal protection, and other related tests and procedures

(g)(3)(i)(A) Initial TB skin testing and medical history (NOTE: Annual skin testing and medical histories are not required)

(g)(3)(i)(B) Medical history, TB skin testing and follow-up for employees who develop signs or symptoms of TB

(g)(3)(i)(C) Medical history, TB skin testing and medical management and follow-up of employees after an exposure incident

(g)(4)(i) Notification of employee and employer as soon as feasible about infectious TB disease status of the employee

(g)(4)(ii) Notification of employees about previously unidentified individuals with infectious TB

(g)(4)(iii) Determination of drug susceptibility of *M. tuberculosis* source after an exposure incident

(g)(4)(iv) Investigations of exposure incidents and TB skin test conversions

(g)(5)(i, ii & iv) Medical removal and protection of benefits for individuals with infectious TB

(g)(6)(i & ii) Information provided to the physician or other licensed health care professional

(g)(7)(i–iii) Physician or other licensed health care professional's written opinion

##### *(h) Communication of Hazards and Training*

(h)(1)(i) If temporary isolation is used, label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis*

(h)(2)(i)(A) If temporary isolation is used, post signs at entrance to temporary isolation

(h)(2)(ii) When temporary isolation room or area is vacated by an individual with suspected or confirmed infectious TB, ventilate for an appropriate period

(h)(2)(iii) Signs for temporary isolation rooms or areas must have a stop sign with the legend "No Admittance Without Wearing a Type N95 or More Protective Respirator"

(h)(3)(i–viii) Annual training with specified elements for employees with occupational exposure

##### *(i) Recordkeeping*

(i)(1)(i–iv) Medical Records

(i)(2) OSHA Illness and Injury Records

(i)(3)(i & ii) Training Records

(i)(4)(i–iii) If temporary isolation is used, engineering control maintenance records

(i)(5)(i & ii) Availability of medical and training records

(i)(6)(i & ii) Transfer of records

##### *(k) Dates*

(k)(1) Effective date

(k)(2)(i, ii & iii) Start up dates for exposure control, medical surveillance, information and training, recordkeeping, and work practices and engineering controls

#### **Appendix B to § 1910.1035—Fit Testing Procedures (Mandatory)**

##### **Part I. Approved Fit Test Protocols**

###### *A. Fit Testing Procedures*

The employer shall conduct fit testing using the following procedures. These provisions apply to both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a selection of respirators of various sizes and models.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he or she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted; the most acceptable mask is donned

and worn at least five minutes to assess acceptability. Assistance in assessing acceptability can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of acceptability shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the acceptability of the respirator:

- (a) Position of the mask on the nose,
- (b) Room for eye protection,
- (c) Room to talk;
- (d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

- (a) Chin properly placed;
- (b) Adequate strap tension, not overly tightened;
- (c) Fit across nose bridge;
- (d) Respirator of proper size to span distance from nose to chin;
- (e) Tendency of respirator to slip;
- (f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described in this appendix or other fit check procedures recommended by the respirator manufacturer providing equivalent protection to the procedures in this appendix. Before conducting the negative or positive pressure fit checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns that cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. *Exercise regimen.* Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. *Test Exercises.* The test subject shall perform exercises, in the test environment, while wearing any applicable safety equipment that may be worn during actual

respirator use which could interfere with fit, in the manner described below:

(a) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally.

(b) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) *Moving head up and down.* Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

#### **Rainbow Passage**

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) *Grimace.* The test subject shall grimace by smiling or frowning. (Only for QNFT testing, not performed for QLFT)

(g) *Bending over.* The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) *Normal breathing.* Same as exercise (a). Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

#### **B. Qualitative Fit Test (QLFT) Protocols**

##### **1. General**

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

##### **2. Isoamyl Acetate Protocol**

**Note:** This protocol is not appropriate, by itself, for fit testing particulate respirators. If chosen for use in fit testing particulate respirators, the respirator must be equipped with an organic vapor cartridge, provided the employee will be using the same facepiece in the work setting except that it will be equipped with particulate filters.

(a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) *Isoamyl acetate fit test.* (1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot

diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent the test medium that is not contained will be removed from the general room air.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When the subject wearing the respirator passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self sealing bag to keep the test area from being contaminated.

### 3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts #FT 14 and #FT 15 combined, is adequate.

(2) The test enclosure shall have a 3/4-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as the DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as the DeVilbiss Model 40 Inhalation Medication

Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 13 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

### 4. Bitrex (Denatonium benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because of its current acceptance and past validation. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening. The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # 14 and # 15 combined, is adequate.

(2) The test enclosure shall have a 3/4 inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 13.5 milligrams of Bitrex in 100 ml of 5% NaCl solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex in 200 ml of a 5% solution of NaCl in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A.13 of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

## 5. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate filters (i.e., HEPA, N100, R100, or P100).

(b) No form of test enclosure or hood for the test subject shall be used.

(c) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties.

(d) Break both ends of a ventilation smoke tube containing stannic chloride. Attach one end of the smoke tube to an aspirator squeeze bulb and cover the other end with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(e) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his or her eyes closed while the test is performed.

(f) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject beginning at least 12 inches from the facepiece and gradually moving to within one inch, moving around the whole perimeter of the mask.

(g) The exercises identified in section I.A.13 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(h) Each test subject passing the smoke test without evidence of a response (involuntary cough) shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he or she reacts to the smoke. Failure to evoke a response shall void the fit test.

(i) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

## C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable:

(1) Quantitative fit testing using a non-hazardous challenge aerosol (such as corn oil or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.

(2) Quantitative fit testing using ambient aerosol as the challenge agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit.

(3) Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

### 1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean, maintained and

calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

### 2. Generated Aerosol Protocol

(a) *Apparatus.* (1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil or sodium chloride) or gases or vapors as test aerosols shall be used for quantitative fit testing.

(2) *Test chamber.* The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter (i.e., HEPA, N100, R100, P100) supplied by the same manufacturer in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used, provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least 1/4 inch.

(7) The test set-up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and

of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency or sorbent) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

(b) *Procedural Requirements.* (1) When performing the initial positive or negative pressure fit check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these fit checks.

(2) An abbreviated screening QLFT test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another method that can be used to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability

may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable challenge concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable fit typical of normal use.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(c) *Calculation of fit factors.* (1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(2) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 8 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak penetration method, which is the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise also meet the requirements of the average peak penetration method.

(ii) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(iii) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise is another method. This includes computerized integration.

(iv) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor is also appropriate. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

Where  $ff_1$ ,  $ff_2$ ,  $ff_3$ , etc. are the fit factors for exercise 1, 2, 3, etc.

(4) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(5) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced if there is any indication of breakthrough by a test agent.

### 3. Ambient Aerosol Condensation Nuclei Counter (CNC) Protocol

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, model, and size that is intended to be used and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer TSI also provides probe attachments (TSI sampling adapters) that

permit fit testing in an employee's own respirator. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The Agency does not recommend the use of homemade sampling adapters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

#### (a) Portacount Fit Test Requirements.

(1) Check the respirator to make sure the respirator is fitted with a high efficiency filter (i.e., HEPA, N100, R100, P100) and that the sampling probe and line are properly attached to the facepiece.

(2) Instruct the person to be tested to don the respirator several minutes before the fit test starts. This purges the particles inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual should have already been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendencies for the respirator to slip; Self-observation in a mirror to evaluate fit; and respirator position.

(4) Have the person wearing the respirator do a fit check. If leakage is detected,

determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same type of respirator.

(5) Follow the instructions for operating the Portacount and proceed with the test.

(b) *Portacount Test Exercises*—(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution so as not to hyperventilate.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute.

(6) *Grimace*. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) *Bending Over*. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist.

(8) *Normal Breathing*. Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(c) *Portacount Test Instrument*. (1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) A record of the test needs to be kept on file assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

#### 4. Controlled Negative Pressure (CNP) Protocol

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator.

The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Dynatech Nevada also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his or her breath, then an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the challenge pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to

determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator.

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) *CNP Fit Test Requirements*—(1) The instrument shall have a non-adjustable challenge pressure of 15.0 mm water pressure.

(2) The CNP system defaults for challenge pressure shall be tested at  $-0.58$  inches of water and the modeled inspiratory flow rate shall be 53.8 liters per minute.

**Note:** CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The test subject shall be trained to hold his or her breath for at least 20 seconds.

(6) The test subject shall don the test respirator without any assistance from the individual who conducts the CNP fit test.

(7) The QNFT protocol shall be followed according to section I.C.1 except that the CNP test exercises shall be used.

(b) *CNP Test Exercises*—(1) *Normal breathing*. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) *Deep breathing*. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution not to hyperventilate. After the deep breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) *Turning head side to side*. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) *Moving head up and down*. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject needs to hold head full up and hold his or her breath for 10 seconds

during test measurement. Next, the subject needs to hold head full down and hold his or her breath for 10 seconds during test measurement.

(5) *Talking*. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) *Grimace*. The test subject shall grimace by smiling or frowning for 15 seconds. After the grimace exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(7) *Bending Over*. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) *Normal Breathing*. Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) *CNP Test Instrument*.—(1) The test instrument shall have an effective audio warning device when the test subject fails to hold his or her breath during the test. The test shall be terminated whenever the test subject failed to hold his or her breath. The test subject may be refitted and retested.

(2) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

#### Part II. Facepiece Fit Checks (Nonmandatory)

A. *Positive pressure check*. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure check*. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold

the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

**Appendix C to § 1910.1035—Ventilation Chart for Isolation Rooms or Areas (Mandatory)**

Under paragraph(d)(5)(vii), the proposed standard requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection. The following appendix is an excerpt of the CDC recommendations of the air changes per hour (ACH) and time in minutes required for removal efficiencies of 90%, 99% and 99.9% of airborne contaminants (Ex. 4B). This table specifies the time necessary to ventilate an isolation room or area, for a given air change per hour, before allowing employees to enter without respiratory protection.

Minutes required for a removal efficiency of:

ACH	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

This table has been adapted from the formula for the rate of purging airborne contaminants. (Ex. 5-100) Values have been derived from the formula  $t_1 = [\ln(C_2 + C_1) + (Q + V)] \times 60$ , with  $t_1 = 0$  and  $C_1 + C_2$ —(removal efficiency + 100), and where:

- $t_1$  = initial timepoint
- $C_1$  = initial concentration of contaminants
- $C_2$  = final concentration of contaminants
- $Q$  = air flow rate (cubic feet per hour)
- $V$  = room volume (cubic feet)
- $Q + V$  = ACH

The times given assume perfect mixing of air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor (Ex. 5-99). The required time is derived by

multiplying the appropriate time for the table by the mixing factor that has been determined for the booth or room. The factor and required time should be included in the operating instructions provided by the manufacturer of the booth or enclosure, and these instructions should be followed.

**Appendix D to § 1910.1035—Ultraviolet Radiation Safety and Health Provisions (Nonmandatory)**

This appendix sets forth non-mandatory guidelines on safety and health provisions concerning the use of ultraviolet germicidal irradiation (UVGI). Because the effectiveness of UVGI systems will vary, and the interaction of factors such as humidity, UV intensity, duration of exposure, lamp placement, and air mixing have not been adequately evaluated, employers may choose to use UVGI systems as supplements to the administrative, engineering, and work practice controls required by this standard. OSHA does not consider UVGI as a substitute or replacement for:

- (1) Negative pressure;
- (2) Exhaust of contaminated air directly to the outside away from intake vents and employees;
- (3) High efficiency particulate air (HEPA) filtration of contaminated air before being recirculated to the general facility or exhausted directly outside (permitted only when it cannot be safely discharged).

**UVGI Systems**

The intent of UVGI systems is to kill or inactivate airborne microorganisms, including *M. tuberculosis*. Two types of systems are generally employed for this purpose: duct irradiation systems, and upper room air irradiation systems. (Floor level UVGI systems are used in some laboratory facilities, but are not specifically discussed in this appendix.) UVGI systems utilize low-pressure mercury vapor lamps that emit radiant energy predominantly at a wavelength of 254 nanometers (nm).<sup>1</sup> In duct irradiation systems, one or more UV tubes are positioned within a duct to irradiate air being exhausted from a room or facility. In upper room air irradiation systems, UV lamps are suspended from a ceiling or mounted on a wall. The lamps are positioned such that air in the upper part of the room is irradiated. The intent is to minimize the levels of UV radiation in the lower part of the room where the occupants are located. These systems rely on air mixing to move the air from the lower portion of the room to the upper portion of the room where it can be irradiated.

**Safety and Health Considerations**

UV radiation at 254 nm is absorbed by the outer surfaces of the eyes and skin. Overexposure to UVGI can result in photokeratitis (inflammation of the cornea) and/or conjunctivitis (inflammation of the conjunctiva).<sup>2</sup> Keratoconjunctivitis is a reversible condition but can be debilitating while it runs its course. Because there is a latency period before health effects are observed, workers may not recognize this as an occupational injury. Symptoms may include a feeling of sand in the eyes, tearing, and sensitivity to light. Overexposure to the skin to UVGI also can result in erythema (reddening). This effect is also reversible, with recovery occurring within 2 to 3 days.

In 1992, the International Agency for Research on Cancer (IARC) classified UV-C radiation as "probably carcinogenic to humans (Group 2A)".<sup>3</sup> This classification was based on studies suggesting that UV-C radiation can induce skin cancers in animals, DNA and chromosome damage in human cells in vitro, and DNA damage in mammalian skin cells in vivo. In the animal studies, exposure to UV-B could not be excluded; however, the observed effects were greater than expected for UV-B alone.<sup>3</sup> Laboratory studies have shown that UV radiation can activate human immunodeficiency virus (HIV) gene promoters in human cells (genes in HIV that prompt replication of the virus); however, the implications of these findings for humans exposed to UVGI are unknown.<sup>4,5,6,7,8,9</sup>

**Occupational Exposure Criteria for Ultraviolet Radiation**

In 1972, the National Institute for Occupational Safety and Health (NIOSH) published a recommended exposure limit (REL) for UV radiation to prevent adverse effects on the eyes and skin.<sup>2</sup> The NIOSH REL for UV radiation is wavelength dependent because different wavelengths of ultraviolet radiation have differing abilities to cause skin and eye effects. The American Conference of Governmental Industrial Hygienists (ACGIH) also has a Threshold Limit Value<sup>®</sup> for UV radiation that is identical to the REL in this spectral region.<sup>10</sup> It should be noted that photosensitive individuals and those concomitantly exposed to photosensitizing agents (including certain medications) may not be protected by these occupational exposure limits.<sup>10</sup>

The term relative spectral effectiveness is used to compare UV sources with a source producing UV radiation only at 270 nm, the wavelength of maximum sensitivity for corneal injury. For example, the relative spectral effectiveness ( $S_{\lambda}$ ) at 254 nm is 0.5; therefore, twice as much energy is required at 254 nm to produce the same biological effect at 270 nm. Thus, at 254 nm, the NIOSH REL is 0.006 joules per square centimeter (J/cm<sup>2</sup>), and at 270 nm it is 0.003 J/cm<sup>2</sup>.

For germicidal lamps, proper use of the REL (or TLV) requires that the measured irradiance level (E) in microwatts per square centimeter ( $\mu\text{W}/\text{cm}^2$ ) be multiplied by the relative spectral effectiveness at 254 nm (0.5) to obtain the effective irradiance ( $E_{\text{eff}}$ ). The maximum permissible exposure time (t) for workers with unprotected eyes and skin can then be read directly from Table 1 for selected values of  $E_{\text{eff}}$ , or can be calculated (in seconds) by dividing 0.003 J/cm<sup>2</sup> (the NIOSH REL at 270 nm) by  $E_{\text{eff}}$  in W/cm<sup>2</sup>. To protect workers who are exposed to germicidal UV radiation for eight hours per day, the measured irradiance (E), should be  $\leq 0.2 \mu\text{W}/\text{cm}^2$ . This is calculated by using Table 1 to obtain  $E_{\text{eff}}$  (0.1  $\mu\text{W}/\text{cm}^2$ ), and then dividing by  $S_{\lambda}$  (0.5).

**Example:** If the measured irradiance was 0.4  $\mu\text{W}/\text{cm}^2$ , then the maximum permissible exposure time is 15,000 seconds, or approximately 4 hours as shown below:

$$\begin{aligned}
 E_{\text{eff}} &= E \times S_{\lambda} \\
 &= 0.4 \mu\text{W}/\text{cm}^2 \times 0.5 \\
 &= 0.2 \mu\text{W}/\text{cm}^2 \\
 t(\text{sec}) &= \frac{0.003 \text{ J}/\text{cm}^2}{E_{\text{eff}} (\text{W}/\text{cm}^2)} \\
 &= \frac{0.003 \text{ J}/\text{cm}^2}{0.2 \times 10^{-6} \text{ W}/\text{cm}^2} \\
 &= 15,000 \text{ sec. (approx 4 hours)}
 \end{aligned}$$

TABLE 1—MAXIMUM PERMISSIBLE EXPOSURE TIMES FOR SELECTED VALUES OF  $E_{\text{eff}}$ .

Duration of exposure per day	Effective irradiance $E_{\text{eff}}$ ( $\mu\text{W}/\text{cm}^2$ )
8 hrs .....	0.1
4 hrs .....	0.2
2 hrs .....	0.4
1 hr .....	0.8
30 min .....	1.7
15 min .....	3.3
10 min .....	5.0
5 min .....	10.0

This table was adapted from a table in *Criteria for a Recommended Standard . . . Occupational Exposure to Ultraviolet Radiation*.<sup>2</sup> Maximum permissible exposure times refer to workers with unprotected eyes and skin.

**Measurement Equipment.** A UV radiometer can be used to measure the irradiance levels in the room and to document lamp output. Some UV measurement systems rely on the use of a detector or probe which is most sensitive at 254 nm, while others rely on the use of a broad-band radiometer with an actinic probe. The latter instrument has a response that accounts for the wavelength dependence of the REL, allowing direct measurement of the effective irradiance ( $E_{\text{eff}}$ ).<sup>11</sup> While both types of systems are acceptable, persons performing the measurements should be aware of the differences so that the measurements obtained are appropriately compared with the recommended occupational exposure limits. Equipment used to measure UV radiation should be maintained and calibrated on a regular schedule, as recommended by the manufacturer.

**UVGI Safety and Health Program**

Employers should consult with persons having expertise in industrial hygiene, engineering, and/or health physics before designing and installing UVGI systems. In addition, the following guidelines should be used to protect workers from overexposure to UV radiation. These guidelines should be incorporated into a UVGI safety and health program. One person should be given responsibility for managing the program.

(1) Exposure Monitoring

a. **Upper Air Irradiation Systems.** Before an upper air UVGI system is activated in the workplace, exposure monitoring should be conducted to determine the levels of UV

radiation in the room. The UV radiation levels will be affected by the position of the lamp, fixture design (including presence and position of baffles and louvers), tube type, room dimensions, and presence of UV absorbing or reflecting materials. At a minimum, UV radiation measurements should be made with the detector directly facing the lamp at head or eye height (with maximum levels recorded), to assess the potential UV exposure to the eyes, the most sensitive organ. Because workers typically move around a room or area while performing their duties, it is often not possible to predict how long a worker will be in a given location, nor is it practical to attempt to control exposures administratively by limiting the duration of exposure at a given location. Therefore, the exposure monitoring should be conducted in representative locations to adequately assess the range of potential worker exposures. Worker exposures should be maintained below the NIOSH REL<sup>2</sup> and ACGIH TLV<sup>10</sup> for ultraviolet radiation.

UV radiation measurements should be made: (1) at the time of initial installation of the UVGI system; (2) whenever new tubes are installed; and (3) whenever modifications are made to the UVGI system or to the room that may affect worker exposures (i.e., adjustment of fixture height, location, or position of louvers; addition of UV absorbing or reflecting materials; and changes in room dimensions).

UV radiation measurements may also be obtained to document the UV output of the lamp for tube replacement or other purposes. Because these types of measurements are commonly done close to the source of the UV output, the person obtaining the measurements may be exposed to high levels of UV radiation. UV radiation levels up to 840  $\mu\text{W}/\text{cm}^2$  (420  $\mu\text{W}/\text{cm}^2$  effective irradiance) have been measured at a distance of four inches from the face of a 30W tube that had been in use several months.<sup>12</sup> Using the NIOSH REL, this exposure level would result in a permissible exposure time of only 7 seconds for workers with unprotected eyes and skin. Because of the high irradiance levels, it would not be practical in this situation to control UV exposures by limiting exposure duration. Skin and eye protection would be needed to protect the worker when making UV measurements close to the source.

b. **Duct Irradiation Systems.** Duct irradiation systems frequently involve the placement of several UV tubes within a section of duct work. Thus, workers who have contact with these lamps are potentially exposed to high levels of UV radiation. This presents a hazard for maintenance workers and others who are responsible for documenting the UV output of these lamps. At one facility where a duct irradiation system was used, UV radiation levels up to 950  $\mu\text{W}/\text{cm}^2$  were measured at a distance of approximately three feet from a bank of four 39W UV tubes.<sup>11</sup> In this situation, the NIOSH REL would be exceeded in about 6 seconds; therefore, skin and eye protection would be needed to prevent worker overexposures to UV radiation. Most UV exposures resulting from duct irradiation systems can be avoided

by inactivating the lamps before maintenance work is done, and providing an access port for viewing the lamps during preventive maintenance inspections. These control measures are discussed further in the Control Methods section of this appendix.

(2) Control Measures

The following control measures should be used to prevent or reduce UV exposures.

a. **Engineering Controls.** 1. In upper air irradiation systems, the UV tubes in the fixture should not be visible from any usual location/position in the room. The fixtures should contain baffles or louvers that are appropriately positioned to direct the UV irradiation to the upper air space. The baffles and louvers should be constructed so that they cannot be easily bent or deformed.

2. In upper air irradiation systems, all highly UV reflecting material should be removed, replaced, or covered. Reflectance values for various materials have been published.<sup>13</sup> Etched aluminum and chromium are examples of materials that have high reflectance values (88 and 45% reflectance, respectively) for 254 nm radiation. Unpainted white wall plaster is reported to have reflectance values of 40–60%.<sup>13</sup>

3. UV-absorbing paints (such as those containing titanium dioxide) can be used on ceilings and walls to minimize reflectance of UV in the occupied space, as needed.

4. The on/off switch for the UVGI lamps should not be located on the same switch as the general room lighting. In addition, these switches should be positioned in such a location that only authorized persons have access to them and they should be locked to ensure that they are not accidentally turned on or off.

5. In duct irradiation systems, there should be an access panel for conducting routine maintenance, monitoring, and cleaning. This access panel should have an interlock or other device to ensure that the tubes are deactivated whenever the panel is opened. To prevent unnecessary UV exposures to maintenance personnel, this port should have a window for viewing the tubes during routine inspections. Ordinary glass (not quartz) and plastics (polycarbonate and polymethylmethacrylate) are sufficient to filter out the UV radiation.<sup>14</sup>

6. All UVGI systems should be inactivated prior to maintenance activity in the affected areas, such as when maintenance workers replace lamps or when entering the upper air space for room maintenance, renovation, or repair work.

b. **Personal Protective Equipment.** UV exposures should be maintained below existing recommended levels. Despite the use of the engineering controls listed above, there may be situations when worker exposures exceed the NIOSH REL, such as when UV measurements are being made close to the lamp source in order to document lamp output, or when maintenance procedures must be performed in areas where UVGI systems are activated. In these and other situations where the NIOSH REL is exceeded, personal protective equipment is needed to prevent worker overexposure to UV radiation. This includes the use of UV-absorbing eyewear with side-shields, head,

neck, and face covering opaque to UV radiation, gloves, and long-sleeved garments. The weave of the fabric has been shown to be the major factor affecting transmission of UV radiation,<sup>15</sup> thus, tightly woven fabrics are recommended. UV-absorbing sunscreens

with solar-protection factors of 15 or higher may help protect photosensitive persons.<sup>16</sup>

(3) Labeling

Warning labels should be placed on UV lamp fixtures in upper air irradiation systems and on access panels in duct irradiation systems to alert workers and other room

occupants to this potential hazard. These warning labels should be of sufficient size to be visible to room occupants and should be in the appropriate language(s). Examples of warning labels are shown below:

BILLING CODE 4510-26-P

BILLING CODE 4510-26-C

**CAUTION**  
**HIGH INTENSITY ULTRAVIOLET ENERGY**  
**PROTECT EYES AND SKIN**

**CAUTION**  
**HIGH INTENSITY ULTRAVIOLET ENERGY**  
**TURN OFF LAMP BEFORE ENTERING**  
**UPPER ROOM OR DUCT**

(4) Training

All workers who have potential exposure to UV radiation from UVGI systems should be receiving training on the hazards, relevant symptoms, and precautions concerning exposure. This training should include specific information on:

- a. The rationale for use of UVGI and general principles of operation, including its limitations;
- b. Control measures used to prevent or reduce UV radiation exposure;
- c. Health effects associated with overexposure to UV radiation (including the potential for additive exposure from other UV sources, such as solar radiation and welding);
- d. Recognition of the symptoms of eye and skin damage; and
- e. Special precautions to be taken by workers to prevent overexposure to UV radiation (including the use of personal protective equipment).

(5) Medical Recommendations

The worker's medical history should be obtained to determine if the worker suffers from any condition that may be exacerbated by exposure to UV radiation. Workers should be advised that any eye or skin irritation that develops after acute exposure to UV radiation, or any skin lesion that appears on skin repeatedly exposed to UV radiation should be examined by a physician.

(6) Recordkeeping

The employer should maintain accurate and complete records pertaining to the following:

- a. Exposure monitoring;
- b. Instrument calibration;
- c. Documentation of health effects;
- d. Training;
- e. Maintenance of UVGI systems, including cleaning and replacement of tubes.

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**Appendix E to § 1910.1035—  
Performance Monitoring Procedures for  
HEPA Filters (Nonmandatory)**

This appendix offers nonmandatory guidance on design considerations and performance monitoring of HEPA filters used in air systems that carry air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (e.g., recirculation into building circulating air system, exhausting outdoors near air intakes, etc.).

Both OSHA and CDC recommend against the recirculation of air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* into the general circulating air system of the building or other opportunities where such air may become entrained into the circulating air system (e.g., outdoor exhausting near intakes, transfer to heat wheels, etc.). When recirculation is unavoidable, the air should be cleaned with HEPA filtration. In order to assure effective functioning of these systems, they should be properly designed, installed, and maintained.

**Design of HEPA Filtration Systems**

The following elements should be considered for incorporation into the design of HEPA filtration systems:

1. Provide upstream prefiltering to reduce dust that may plug the HEPA filter.
2. Provide worker-entry into housings for visual examinations and probe scanning for leaks of filter media and frame-to-filter interfaces. In addition, adequate access should be provided to allow for replacement of the HEPA filters and pre-filters without contaminating the work area by unintentional jarring or dropping of the filters.
3. Provide devices for measuring HEPA filter loading (e.g., pressure differential across a filter).
4. Provide appropriate mounting frames and seals to minimize frame-to-filter leakage.
5. Specify filter media to match operating criteria (e.g., face velocity, volumetric flow rate, pressure drop, etc.).
6. Design upstream and downstream duct to facilitate performance monitoring (e.g., good air mixing for uniform dispersal of challenge aerosols, sectioning to allow isolation of leaks, etc.).
7. HEPA filters must operate in dry airstreams. Tests have shown that exposure

to high humidity for a period of five hours will result in a threefold increase in particle penetration.

#### Maintenance of HEPA Filtration Systems

HEPA filtration systems are generally passive systems without moving parts, so the majority of filter maintenance activities are associated with performance monitoring. In terms of performance monitoring, HEPA filters are to be monitored for *filter loading* and for possible *leakage* every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness. Leaks in HEPA filters can occur in the following ways: (1) in the filter media, (2) in the bond between media and frame, (3) in the frame gasket, (4) in the support frame, and (5) in between the frame and the wall.

Testing of HEPA filters after installation is used to detect leaks associated with shipping damage and with installation problems such as handling damage, variations in gasket thickness and poorly formed gasket corners.

Periodic testing detects deterioration of components, relaxation of gaskets, clamping devices, weld cracks or other leaks that may develop during use. This deterioration will take place even if the system is not on-line and in use.

Penetration is related to filter efficiency "E" by the equation:

$$E=100(1-P)\%$$

Therefore, an efficiency of 99.97% is equivalent to  $P=0.0003$ .

#### Other Filter Testing Methods

There are many recognized HEPA filter testing standards. Most of these standards utilize DOP aerosol to challenge the HEPA filters and provide penetration performance data for 0.3  $\mu\text{m}$  size particles. Since TB droplet nuclei range in size from 1 to 5  $\mu\text{m}$ , the DOP aerosol challenge is indicative of droplet nuclei penetration. Some manufacturers may provide bench test data for filtration efficiency versus particle size which may be useful information when selecting filters but may be difficult to duplicate in the field for in-service testing. These test standards include:

1. Standard UL 586, *High-Efficiency, Particulate, Air Filter Units* as published by Underwriters Laboratories, 1990 (Ex. 7-227). This test is designed for bench testing at the factory and does not include the frame-to-filter bypass leakage measured by in-service testing. This test method uses a light beam-photocell combination (photometer) to measure the density of the DOP smoke in the air.

2. Standard ASTM F1471-92, *Air Cleaning Performance of a High-Efficiency Particulate Air-Filter System*, as published by the American Society for Testing and Materials, 1993 (Ex. 7-222). This test can be used in the field for in-service testing of HEPA filters. This test method utilizes a laser aerosol spectrometer which can count particles by particle size.

#### Monitoring for Filter Loading

HEPA filtration systems become loaded with particulate matter through use. Although this loading improves particulate arrestance, it eventually increases the pressure drop across the filter assembly. Consequently, the flow capacity begins to diminish and bypass leakage at the frame-to-filter interface increases. Therefore, these filters need to be monitored and changed.

It is imperative that the differential pressures across the HEPA filter remain below the maximum operating resistance level set by the manufacturer and stamped on the filter label. Filter penetration by contaminants can occur when HEPA filters exceed the manufacturer's maximum resistance rating, making the system ineffective.

The operating resistance level is determined by measuring the pressure differential across the filter through use of a pressure sensing device. Measurements of differential pressure across the HEPA filters should be made when the prefilters have been removed. These measurements should be used to predict future HEPA filter replacement or for determining the need for immediate HEPA filter replacement.

$$P = 100 \left( \frac{\text{downstream concentration}}{\text{upstream concentration}} \right) \%$$

3. Standard NSF-49, Appendix B, *HEPA Filter Leak Test for Biosafety Cabinets*, as published by the National Sanitation Foundation (Ex. 7-226). This test is designed for in-service HEPA filter testing and utilizes a portable photometer probe which can be passed over the filter frame perimeter to check for bypass leaks.

Unfortunately, there are hazards associated with exposure to DOP. The Material Safety Data Sheet for DOP reports irritation, nausea and numbness as symptoms associated with DOP inhalation. Nausea, diarrhea, reproductive effects, liver enlargement, and cancer are effects associated with ingestion of DOP. Therefore, performance testing that does not utilize DOP should also be considered.

Alternative methods are in use and being developed that capitalize on recently developed optical particle counters (e.g., lasers) that can count particles at specified sizes. For example, the National Environmental Balancing Bureau (NEBB) publishes *Procedural Standards for Certified Testing of Clean rooms*' Section 8.3 presents an *Ambient Particle Aerosol Challenge Method* that utilizes new-generation optical particle counters to measure upstream and downstream concentrations of particles of a specified size (Ex. 7-228). Only ambient air is measured and no aerosol is generated. This method may have merit for TB applications because ambient air has a statistically significant quantity of particles less than 3.0  $\mu\text{m}$ , but at the same time, this high number of particles may overload the instrument.

Because a dark DOP smoke is not required to attenuate light as is the case with a photometer, recently developed optical

Additional control measures can be used to detect a differential pressure that exceeds the maximum operating resistance which signals the alarm's set point (i.e., audible/visual alarms or computerized error messages).

All pressure measurements should be logged and retained in accordance with paragraph (i)(4)(ii) of this standard.

#### Monitoring for In-service Filter Leakage

In CDC's "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities" [Ex. 4B], the di-octyl phthalate (DOP) penetration test as described in Chapter 25 of the *1992 Systems Handbook from the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)* is offered as a method of performance monitoring HEPA filters. The basis of this well-recognized test is to challenge a HEPA filter assembly with a uniformly distributed cloud of 0.3  $\mu\text{m}$  (mass median diameter) DOP aerosol and measure the DOP smoke upstream and downstream with a light-scattering photometer. Penetration "P" through the filter assembly is the performance criterion typically specified and is defined as:

particle counters offer the opportunity for an alternative non-toxic challenge aerosol like that described in the proposed Standard 52.2 *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* from the American Society of Heating, Refrigerating and Air-Conditioning Engineers. This non-toxic challenge aerosol is based upon potassium chloride (KC) particles which are generated in the 0.3 to 10  $\mu\text{m}$  size range (Ex. 7-224).

#### Filter Testing Performance Criteria

The following should be considered when setting performance testing criteria: (1) Failure of a HEPA filter in a recirculating air system can have serious consequences; (2) HEPA filters are more efficient in removing droplet nuclei than DOP due to the larger particle size of droplet nuclei; (3) In-service filter penetration testing should match factory testing that is  $P \leq 0.0003$  for 0.3  $\mu\text{m}$  challenge particle; (4) The differential pressure drop across a HEPA filter from dirt loading should never exceed the maximum operating resistance set by the manufacturer and stamped on the filter label; (5) Penetration should not exceed 0.0001 when performing localized penetration scanning with a photometer probe around filter frames and across the filter face.

#### Appendix F to § 1910.1035—A Guide to Writing an Exposure Control Plan (Non-mandatory)

A Guide to Writing an Exposure Control Plan is a non-mandatory appendix developed to assist employers in complying with § 1910.1035 Occupational Exposure to

Tuberculosis. This standard requires employers to have a written Exposure Control Plan (ECP) documenting procedures they use to control exposure to Tuberculosis (TB).

The following guide aids employers in writing the required ECP by reviewing the standard's requirements and providing examples of policy, narrative statements, and a "fill-in-the-blank" sample ECP. Before using this guide, employers will need to read the standard. Once familiar with the standard, they can use this appendix to develop a program specific to their facility.

Employers are not required to use the sample ECP included in this guide. They may develop their own format and may include the TB ECP in their overall infection control plan. However, the ECP must include all OSHA required information and all policies and procedures in the plan must be implemented whether the ECP is a separate plan or included in another document. If the TB elements are included in an overall infection control plan, the employer must develop an index referring the reader to their locations within that plan. Since the elements in the sample ECP are the minimum necessary to meet the standard's requirements, employers may enhance the sample with more comprehensive procedures if they wish.

OSHA developed the guide to help employers comply with the standard. The information contained in this Guide to Writing an Exposure Control Plan for Occupational Exposure to Tuberculosis is not considered to be a substitute for the OSH Act or any provisions of the OSHA Standard. It provides general guidance for a particular standards-related topic and should not be considered a legal authority for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

Employers who have additional questions concerning this standard may contact the nearest OSHA office.

#### How to Use This Guide

A Guide to Writing An Exposure Control Plan has two components: Notes to the Employer and a Sample Exposure Control Plan. Notes to the Employer consists of explanations for some of the standard's ECP requirements, guidance about writing an ECP and information about practices common to a variety of employers. Notes to the Employer is organized to correspond chronologically to the Sample Exposure Control Plan.

The Sample Exposure Control Plan contains examples of policy statements and procedures. It has a number of sections and is organized in program development form. Although it does not always follow the exact sequence of the standard, all elements of the standard are included. Each section of the Sample ECP is cross-referenced to the specific provisions of the standard using the letter and numerical paragraph designation. The Sample ECP has blank spaces to be completed by the employer with site-specific information.

The standard provides a tiered approach to compliance. Not all provisions apply to all facilities. This approach accommodates

facilities with varying factors. OSHA's sample ECP accommodates the difference between these types of facilities.

(1) The first tier is employers (other than the operators of a laboratory) that do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have had no cases of confirmed TB in the past 12 months and are located in counties that in the past two years have had zero cases of confirmed infectious TB in one year and fewer than 6 cases of confirmed infectious TB in the other year. Work settings in this tier have presented minimal occupational exposure and therefore may choose to comply with only a limited number of provisions. (See Appendix A). Required elements for these facilities are underlined in the sample ECP. They include: procedures for exposure determination, prompt identification of individuals with suspected or confirmed infectious TB, exposure incident reporting, and procedures for referring individuals with suspected or confirmed TB to facilities with appropriate isolation capabilities.

Employers who wish to have a minimal exposure control plan as described in Appendix A must document the number of cases of tuberculosis reported in their county in the previous twelve month reporting period and the number of individuals with confirmed tuberculosis encountered in the facility in the previous twelve months.

(2) The second tier encompasses employers who use early identification and transfer procedures rather than admit individuals with suspected or confirmed infectious TB. They typically do not have AFB isolation rooms or autopsy rooms or conduct high-hazard procedures in their facility. These facilities can omit the sections about AFB isolation rooms and engineering controls since these provisions do not apply to them unless they have to use temporarily isolate when it is not possible to transfer individuals with suspected or confirmed infectious TB within five hours. Paragraph (c)(2)(ii) lists the requirements of the ECP for this type of facility. In the sample ECP, certain sections are starred (\*) to assist facilities that transfer individuals with suspected or confirmed infectious TB within five hours of discovery. These employers may omit the starred sections when writing their ECP.

(3) The third tier covers employers who admit and provide medical services to individuals with suspected or confirmed infectious TB. These employers are required to have AFB isolation rooms and procedures to protect employees working in or around those rooms. In addition, they must have maintenance schedules for engineering controls as well as other protections. Paragraph (c)(2)(iii) lists specific requirements for these facilities. However, if these employers transfer some individuals with suspected or confirmed infectious TB as well as admit and provide medical services for those individuals, the facility must have procedures for the transfer. The sample ECP includes all required ECP elements thus providing guidance to facilities that admit and provide medical services.

#### Sample Exposure Control Plan Notes to the Employer

##### Exposure Control Plan (c)(2)

##### Policies and Program Administration

The standard requires each employer to have a written exposure control plan and to review and update it annually. The Sample Exposure Control Plan has examples of statements reflecting the employer's policy. Blanks are provided for the employer to designate the facility name.

Employers have limited ECP provisions (see Appendix A) if they (1) do not admit or provide medical services to individuals with suspected or confirmed infectious TB, (2) have had no case of confirmed infectious TB in the past 12 months and (3) are located in a county that, in the past 2 years, has had zero cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. (Paragraph (b)). In addition, these employers must determine the number of reported cases in the county for the last twelve month reporting period and record it in the ECP. They must also document the number of confirmed cases of TB in their facilities. The numbers can be recorded in this first section of the ECP.

The written ECP must be accessible to employees, OSHA and NIOSH representatives for viewing and copying as necessary. (Paragraph (c)(2)(vii)) A sample statement regarding the accessibility is written below. OSHA does not require this statement to be written. However, employers may include this type of statement in their ECP to clearly define the company's/ organization's policy.

Sample Statement: Employees and/or OSHA or NIOSH representatives may view the ECP at \_\_\_\_\_ (location of ECP) \_\_\_\_\_ and may copy the plan as necessary.

Designating a specific person to be responsible for maintaining the exposure control plan is not a requirement of the regulation. However, it is a common practice.

Sample Statement: \_\_\_\_\_ (responsible person/department) \_\_\_\_\_ is responsible for maintaining, reviewing and updating the Exposure Control Plan (ECP).

##### Employee Exposure Determination (Paragraph (c)(1)(i)(A))

In paragraph (c)(1)(i) & (ii), OSHA requires employers to review job classifications in their facilities and determine which employees have occupational exposure to infectious TB (Occupational exposure is defined in paragraph (j) of the standard). All TB exposure determinations must be made without regard to the use of respiratory protection.

There are two basic employee job classifications for employers to consider: (1) jobs in which all employees have occupational exposure to infectious tuberculosis because of the very nature of the job such as respiratory therapists and nurses who work on a pulmonary unit and (2) jobs that result in occupational exposure to tuberculosis when certain tasks or procedures are performed; for example, dietary personnel delivering meals to an individual in AFB isolation or housekeeping staff cleaning an AFB isolation room.

All employees in the first job classification are considered to have occupational exposure to infectious TB, so specific job tasks for this classification are not required to be defined. In the second category, however, only some employees may have occupational exposure and, then, only when performing certain tasks. Therefore, OSHA requires the employer to define those tasks. Examples of tasks in which employees may have occupational exposure to TB include: transporting patients; entering occupied isolation areas to clean or deliver meals; performing maintenance on HVAC systems that exhaust air from occupied AFB isolation rooms; and, performing suctioning and/or aerosolized treatments on patients with suspected/confirmed TB. Tasks may be listed in closely related groups or as individual tasks.

Not all employers have both types of job classifications. Employers are not required to complete both categories unless there are job classifications that pertain to each.

#### Employee Notification of TB Hazards (Paragraph (c)(2)(i)(B))

The standard requires that the employer include procedures in the ECP "for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions."

The employer must assure that employees have enough information to take proper precautions against exposure to TB. However, the employer must also consider the medical confidentiality of the infectious individual and assure that this confidentiality is maintained to the extent possible and consistent with applicable laws.

Employers are expected to define responsibilities and outline procedures used to inform employees of TB hazards. OSHA requires that an employer notify employees by posting signs and labeling ventilation ducts. (Paragraphs (h) (1) & (2))

The following sample statements provide an abbreviated example of some procedures that might be used in a health care facility. These statements are not OSHA requirements but examples.

*Sample Statement:* As soon as infectious TB is suspected the nurse in charge of the unit must be informed. The nurse in charge of the unit also must assure that (1) the individual is placed in an AFB isolation room marked with a sign: "No Admittance Without Wearing a Type N95 of More Protective Respirator"; (2) the nursing supervisor and infection control specialist are notified, (3) all staff working on the unit are notified, and (4) proper equipment is obtained.

If the individual with suspected or confirmed infectious TB must be transferred to be placed in an isolation room, all procedures required by this ECP will be utilized, such as masking the individual or if that cannot be done, having the employee don a respirator.

The nurse in charge of the unit immediately notifies the facility engineer to assure that (1) the engineering controls are

working properly and (2) all maintenance and contract employees are informed of the potential TB hazard. \_\_\_\_\_ (maintenance engineer) \_\_\_\_\_ is to immediately check to assure that all ducts carrying exhaust air from the room occupied by the individual with suspected or confirmed infectious TB are labeled "Contaminated air—Respiratory Protection Required".

Dietary, laboratory, and other test order sheets are specially noted to indicate "Respiratory Isolation—No admittance without an N95 or More Protective Respirator."

In addition to informing their own employees, host employers are required to notify contractors of TB hazards. Some contractors and contracting employees may be required to enter or work in AFB isolation areas or other areas in the facility where occupational exposure is likely to occur or where air systems may reasonably be anticipated to contain aerosolized *M. tuberculosis*. Since host employers know the location of the hazards, they must inform the contractor. (Paragraph (d)(6))

OSHA requires the employer to post signs at the entrance to (1) rooms or areas used to isolate individuals with suspected or confirmed infectious TB, (2) areas where procedures or services are being performed on an individual with suspected or confirmed infectious tuberculosis and (3) clinical/research laboratories where *M. tuberculosis* is present. (Paragraph (h)(2))

Signs must include a picture of a stop sign, have a red background with white lettering and say: "No Admittance Without Wearing a N95 or More Protective Respirator." The employer may include additional language provided the major message on the sign remains clear. (Paragraph (h)(2)(iii))

After the room is vacated, the sign must remain posted at the entrance until the room or area is ventilated, using the USPHS recommendations for removal efficiency of 99.9%, for the time necessary to permit entry without the use of a respirator. See Appendix C of the standard. (Paragraph (h)(2)(ii))

The room does not need to be ventilated and the sign may be removed immediately if both of the following criteria are met (1) the room was occupied by an individual with suspected infectious tuberculosis and (2) that individual is medically determined to be non-infectious. (Paragraph (h)(2)(ii))

If employers have engineering controls, those controls must be labeled appropriately and the labeling procedures must be noted in the ECP. (Paragraph (h)(1))

The type of HVAC system in the facility will determine where ducts are labeled. Ducts that have HEPA filtration must be labeled at all duct access points located prior to the HEPA filter. HVAC systems that exhaust air directly to the outside must be labeled at all access points, fans and exhaust outlets. (Paragraph (h)(1))

Signs at the entrance to clinical or research laboratories and autopsy suites must include the biohazard symbol, name of the laboratory director or other designated responsible person, *M. tuberculosis*, and special requirements for entering the laboratory or autopsy room. In addition, contaminated laboratory wastes must be labeled with the

biohazard symbol or be placed in a red container. (Paragraph (h)(2)(iv))

Although the standard does not require noting this in the ECP, employers may want to document where engineering controls are located in their facility. If an employer chooses to note this, sample verbiage may be:

Sample Statement: \_\_\_\_\_ (list type of engineering controls in place)

\_\_\_\_\_  
engineering controls are used in the Bronchoscopy suite located on the third floor of this building.

OR

There are no high-hazard procedures performed in this facility. There are no engineering controls in place.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

The employer must investigate circumstances surrounding TB Skin Test conversions and exposure incidents to determine the cause and ways to make changes to prevent similar occurrences. (Paragraph (g)(4)(iv))

The procedures used to report and then to evaluate the incident must be included in this section of the ECP. In addition, employees are required to report incidents to a particular department or person. (Paragraph (c)(2)(i)(C)) This information must be included here, also.

Sample Statement: Exposure incidents are to be reported to \_\_\_\_\_ (name and department)

\_\_\_\_\_  
The reporting procedures utilized at \_\_\_\_\_ (organization's name) are:

\_\_\_\_\_  
Procedures for evaluating the circumstances surrounding the exposure incident at \_\_\_\_\_ (organization's name) are:

#### Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) & (iii)(A))

Each facility is required to establish procedures for promptly identifying individuals with suspected or confirmed infectious TB. The standard considers "suspected or confirmed infectious TB" to be:

"A potential disease state in which an individual is known or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. tuberculosis* and to have signs and symptoms of TB; (2) to have a positive acid fast bacilla (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia)". (Paragraph (j))

This definition must be included in the early identification criteria. Although not mandated by OSHA, some employers add high risk factors like IV drug use,

immunocompromised status, recent immigration from Asia, Africa, Latin America, etc.

Some employers use the 1994 CDC *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* to assist in early identification of TB (Ex. 4). These guidelines state, "TB is not distributed evenly throughout all segments of the U.S. population" and defines groups known to have a higher prevalence of TB infection. These high risk groups include "foreign born persons from Asia, Africa, Latin America and the Caribbean; medically underserved populations (e.g. some African-Americans, Hispanics, Asians, and Pacific Islanders, American Indians, and Alaskan Natives); homeless persons; current or former correctional-facility inmates; alcoholics; intravenous drug-users; and the elderly." Persons with certain medical conditions have a greater risk of progression from latent infection to active disease. These medical conditions are defined in the 1994 CDC guidelines as: "HIV infection, silicosis, diabetes mellitus, gastrectomy or jejunum-ileal bypass, being greater than 10% below ideal body weight, chronic renal failure or renal dialysis, immuno-suppression due to drug therapy and some malignancies."

There are several ways to conduct early identification. Many employers use a questionnaire to quickly assess the individual's health status at intake or admission. Some employers located in communities considered to have a high incidence of TB or working with high risk populations use chest x-rays. Since use of a questionnaire is a common practice, OSHA included one in the Sample ECP. This is not mandatory but is a guide for those employers who may wish to develop a questionnaire.

An example of a policy statement referring to use of a questionnaire is:

Sample Statement: \_\_\_\_\_ (organization's name) \_\_\_\_\_ uses the attached questionnaire to assess the individual's health status as related to suspected or confirmed infectious TB. An individual who has two or more of the symptoms of Tuberculosis in addition to a prolonged cough, a positive AFB smear or is known by \_\_\_\_\_ (organization's name) \_\_\_\_\_ or any of its employees to be infected with *M. tuberculosis* is categorized as having suspected or confirmed infectious TB.

Employers Who Transfer (Paragraph (c)(2)(ii))

#### Procedures for Transfer of Individuals With Suspected or Confirmed Tuberculosis

Employers that transfer rather than admit and provide medical services must document their procedures for isolating an individual while awaiting transfer such as segregating and masking the individual and procedures used if the individual cannot be transferred within 5 hours. This includes documenting the type of equipment used (e.g. masks, respirators).

In the remainder of the sample ECP, employers who transfer suspected or confirmed infectious TB within 5 hours of identification may omit starred sections if they do not have isolation rooms and engineering controls.

Employers who do not admit or provide medical services to individuals with

suspected or confirmed infectious TB, have not encountered any individuals with confirmed TB in their facility in the past twelve months and who are located in counties that in the past two years have had zero cases of confirmed TB reported in one year and fewer than 6 cases in the other year and wish to claim reduced responsibilities must be prepared to transfer such individuals. Therefore, the standard requires these facilities to have procedures for transferring an individual with suspected or confirmed infectious TB, if encountered. (Appendix A)

Employers Who Admit and Provide Medical Services (Paragraph(c)(2)(iii))

#### Procedures for Isolating and Managing Care (Paragraph (c)(2)(iii)(B))

The employer must document procedures for isolating individuals with suspected or confirmed infectious TB such as using AFB isolation rooms and procedures for managing care to minimize employee exposure.

Procedures listed in the Sample ECP are limited to the standard requirements. Employers should add any other isolation and segregation procedures used in their facility to assure that their ECP reflects the way they manage isolation and segregation.

Employers who transfer individuals with suspected or confirmed infectious TB do not need to include procedures for isolating and managing care. However, as stated above, they must list procedures for transferring the individual and segregating and masking these individuals while awaiting transfer. In addition, employers who do not perform high hazard procedures in their facilities do not need to notate anything in the high hazard section of the ECP. These employers may wish to enhance their ECP by clarifying their functions, however. A sample of a statement to enhance and clarify is:

Sample Statement: (1) This facility transfers individuals with suspected or confirmed infectious TB within 5 hours of identification, (2) high-hazard procedures are not performed in this facility, (3) there are no engineering controls for TB control at this facility.

Again, the above statements are not OSHA requirements.

Each employer who admits or provides services to individuals with suspected or confirmed infectious TB is required to institute policies and procedures to address the following issues. The procedures in the Sample ECP are an abbreviated version of the OSHA requirements. (Paragraph (c)(2)(iii)(B) (1 through 5)):

- Minimizing the time the suspected/confirmed infectious individual spends outside the AFB isolation room.
- Minimizing the time of employee exposure in AFB isolation rooms or areas by combining as many tasks as possible into one entry.
- Minimizing the number of workers entering AFB isolation rooms.
- Using a properly fitted mask (e.g. surgical mask or valveless respirator) on individuals with suspected or confirmed infectious TB or transporting these individuals in portable containment engineering control when transport or

relocation outside of AFB isolation rooms or areas is unavoidable.

- Delaying of elective transport or relocation.
- Providing services in an AFB isolation room or area to the extent feasible (e.g. portable x-ray).
- Assuring that the individual is returned to the isolation room as soon as is practical after the completion of the service or procedure.
- Delaying elective high-hazard procedures or elective surgery until the individual with suspected or confirmed infectious TB is determined to be non-infectious.

Some facilities may have extensive procedures while others may have less involved procedures. The extensiveness of the procedures is determined by the type of tasks and services provided the individual with suspected or confirmed infectious TB in that facility.

Whatever the procedures are, the employer is expected to assure that the procedures comply with the OSHA requirement and that all procedures are implemented.

\*High-Hazard Procedures (Paragraph (c)(2)(iii)(C))

The ECP must contain a list of high-hazard procedures performed in the facility.

(\*)All high-hazard procedures that may aerosolize *M. tuberculosis* must be performed in an AFB isolation room, an AFB isolation area, or in a special AFB containment booth. Examples of high hazard procedures include bronchoscopy, pulmonary function testing, endoscopy and autopsy on an individual with suspected or confirmed infectious TB.

\*Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

Employers who have engineering controls in any part of their facility must include a maintenance and performance monitoring schedule in this section of the ECP. (Appendix E)

Sample Statement: Engineering controls for infectious TB are inspected, maintained and undergo performance monitoring according to the following schedule:

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#### Clinical and Research Laboratory Biosafety Procedures Paragraph (c)(2)(iv))

OSHA requires that the facility's laboratory director determine and document the biosafety level at which the laboratory operates.

In addition, the laboratory director must determine and document the need for (1) controlled access, (2) anterooms, (3) sealed windows, (4) directional airflow, (5) preventing recirculation of laboratory exhaust air, (6) filtration of exhaust air before discharge to the outside and (7) thimble exhaust connections for biological safety cabinets.

The laboratory director must consult and follow the guidelines found in the OSHA regulation.

Home Health Care or Home-Based Hospice Care (Paragraph (c)(2)(v))

OSHA requires employers of Home Care or Home-based Hospice care to include procedures for prompt identification of individuals with suspected or confirmed infectious TB. In addition procedures to minimize employee exposure to such individuals and a list of any high-hazard procedures performed in the home and procedures for delaying elective high hazards procedures or surgery until the individual is non-infectious must be included in the ECP.

**Sample Exposure Control Plan**

Exposure Control Plan (Paragraph(c)(2))

Policies and Program Administration

*(company name) maintains, reviews and updates the Exposure Control Plan (ECP) at least annually, and whenever necessary to reflect new or modified tasks, procedures and engineering controls \* that affect occupational exposure. The ECP is also updated to reflect new or revised employee positions with occupational exposure.*

*This facility has had \_\_\_\_\_ cases of confirmed TB in the last 12 months.* (Paragraph (c)(2)(vi))

*(b) This facility is located in \_\_\_\_\_ county which has reported cases of TB in the last twelve month reporting period.*

Employee Exposure Determination (Paragraph (c)(2)(i)(A))

*ALL employees in the following job classifications have or may have occupational exposure to TB (Paragraph(c)(1)(i)(A)): JOB TITLE*

*Employees in the following job classifications have or may have exposure to TB when they are performing the listed tasks and procedures (Paragraph (c)(1)(B)):*

JOB TITLE	TASKS/PROCEDURES

Employee Notification of TB Hazard (Paragraph (c)(2)(i)(B))

*(organization's name ) uses the following procedures to assure that all employees with job tasks that offer potential for occupational exposure are informed of the hazard and take proper precautions against exposure to TB.*

(procedures described)

(\* ) \_\_\_\_\_ (responsible person(s)/ department) \_\_\_\_\_ maintains contact with all outside contractors who provide temporary or contract employees who may incur occupational exposure. This allows the contractor to institute precautions to protect his or her employees. These contractors are informed of the TB hazard and the facility's procedures for protecting themselves from exposure.

(\* ) Signs are posted at the entrance to:

(\* ) 1) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB,

(\* ) 2) Areas where procedures or services are being performed on an individual with suspected/confirmed infectious TB, and

(\* ) 3) clinical land research laboratories where M. tuberculosis is present.

(\* ) All signs are red with white text stating "No Admittance Without a Type N95 of More Protective Respirator" and have a picture of a stop sign. (See attached sample).

(\* ) \_\_\_\_\_ (organization's name) \_\_\_\_\_ ensures that warning labels are placed on AFB isolation room exhaust ducts and areas where occupational exposure to TB is expected.

(\* ) All systems carrying air that may be contain aerosolized M. Tuberculosis are labeled at all points where ducts are accessed prior to HEPA filter, at fans and at the discharge outlets of non-HEPA filtered direct discharge systems. The label says: "Contaminated Air—Respiratory Protection Required".

(\* ) \_\_\_\_\_ (organization's name) \_\_\_\_\_ notifies employees entering the laboratory and the autopsy room of the occupational hazards by using signs at the entrance to both these locations. These signs indicate the name and telephone number of the director of the laboratory, infectious agent—M. tuberculosis, and the special requirements for entering the laboratory or autopsy room. The sign displays the Biohazard symbol.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

*All employees must report exposure incidents immediately to (responsible person(s)/department). \_\_\_\_\_ (Organization's name) is responsible for investigating, evaluating, and documenting the circumstances surrounding the exposure incident for instituting changes to prevent similar occurrences.*

The following procedures are used to investigate/evaluate exposure incidents at (organization's name):

Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) and (iii)(A))

*(Organization's name) considers an individual to be suspected of having Infectious TB (unless the individual's condition has been medically determined to result from a cause other than TB) if either the company or any of its employees determine(s)/learn(s)that the individual:*

- has a persistent cough lasting 3 or more weeks with 2 or more signs and symptoms of active infectious TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia),
- has a positive AFB smear,

*Based on the criteria listed above, (Organization's name) utilizes the following procedures for early detection of individuals with suspected/confirmed infectious TB.*

Employers Who Transfer (Paragraph(c)(2)(ii))

Procedures for Transfer of Individuals With Suspected or Confirmed Infectious TB:

*If/when an isolation room is not available at our facility, the individual is transferred within 5 hours of identifying the infectivity to a facility (name of facility) where isolation rooms are available. The following procedures for transfer of an individual with suspected/confirmed infectious tuberculosis are utilized:*

*While awaiting transfer, the individual is masked or segregated to protect employees who are without respiratory protection. (organization's name) uses the following procedures/equipment when masking and segregating an individual with suspected/confirmed infectious TB:*

*If a situation arises and the individual is not able to be transferred within 5 hours of identifying the suspected or confirmed infectious TB, the following procedures, including AFB isolation, are instituted: (list procedures used)*

Employers Who Admit and Provide Medical Services (Paragraph (c)(2)(iii))

Procedures to Isolate and Manage Care (Paragraph(c)(2)(iii)(B))

(\* ) The following procedures are used to isolate individuals with suspected or confirmed infectious TB.

(\* ) All individuals with suspected or confirmed infectious TB are placed in AFB isolation rooms or areas.

(\* ) \_\_\_\_\_ (organization's name) \_\_\_\_\_ uses the following procedures to minimize the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area: \_\_\_\_\_ (detail responsibilities and steps)

(Paragraph(C)(2)(iii)(B)(1))

(\* ) Employee exposure in AFB isolation rooms is minimized by combining tasks the amount of time an employee spends in an AFB isolation room is minimized by \_\_\_\_\_ (list procedures used)

\_\_\_\_\_ (Paragraph (c)(2)(iii)(B)(2))

(\* ) \_\_\_\_\_ (organization's name) \_\_\_\_\_ uses the following procedures, minimizing the number of workers entering AFB isolation rooms:

(\* ) \_\_\_\_\_ (organization's name) \_\_\_\_\_ utilizes the following procedures to delay

transport or relocation within the facility until the individual is considered non-infectious:

(Paragraph (c)(2)(iii)(B)(3))

(\* Services are provided in the patient's room whenever feasible such as portable x-ray and \_\_\_\_\_ (list other services provided in the patient's room to minimize exposure)

(\* This facility uses \_\_\_\_\_ (list the type of engineering controls in use—properly fitted masks or valveless respirators for the patient to be masked or portable containment devices)

on individuals with suspected or confirmed infectious TB when it is necessary to transport or relocate the individual.

(Paragraph (c)(2)(iii)(B)(4))

(\* The following procedures assure that the individual is returned to the AFB isolation room as soon as practical after completion of the procedure \_\_\_\_\_ (list of procedures)

(\* Services that cannot be rendered in the patient's room are provided in and area that meets the requirements for an AFB isolation room.

(\* Elective high-hazard procedures and surgery are delayed until the patient is non-infectious. (Paragraph(c)(2)(iii)(B)(5))

(\* HIGH-HAZARD PROCEDURES (Paragraph(c)(2)(iii)(C))

(\* High-hazard procedures (where TB may be aerosolized) require special precautions to prevent/minimize occupational exposure to infectious TB. The following high-hazard procedures are performed at this facility: \_\_\_\_\_ (list procedures)

(\* Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

(\* The maintenance schedule for engineering controls is as follows:

(\* Daily—Negative pressure areas are qualitatively demonstrated by using smoke trails.

(\* Whenever HEPA filters are changed, the system is inspected and its performance monitored in accordance with current USPHS guidelines. HEPA filters are changed every \_\_\_\_\_ in this facility or whenever

(\* Every six months—HEPA filters in contained air exhaust systems are inspected, maintained and performance monitored in accordance with current USPHS guidelines.

Clinical and/or Research Laboratories (Paragraph (c)(2)(iv))

The \_\_\_\_\_ (type of laboratory—clinical or research) \_\_\_\_\_ operates at biosafety level \_\_\_\_\_ as determined by \_\_\_\_\_ (name of laboratory director) \_\_\_\_\_ for \_\_\_\_\_ (organization's name) \_\_\_\_\_.

This is in accordance with CDC/NIOSH Biosafety in Microbiological and Biomedical Laboratories).

The following controls are in operation in the laboratory at this facility \_\_\_\_\_ (list controlled access, anterooms, sealed windows and other controls required in the standard and determined necessary by the laboratory director)

(c)(2)(v) HOME HEALTH CARE OR HOME-BASED HOSPICE

See the following sections of this sample ECP for information regarding the ECP requirements:

(1) (c)(2)(ii) & (iii)(A) for sample statements regarding the Prompt identification of individuals with suspected or confirmed infectious TB.

(2) (c)(2)(iii) for sample statements re: procedures for minimizing employee exposure.

(3) (c)(2)(iii)(C) for a sample statement regarding high hazard procedures.

The procedures in this Exposure Control Plan minimize the occupational exposure to TB. The procedures for isolating and managing care are used until the individual with suspected or confirmed infectious TB is determined to be non-infectious or until the diagnosis for TB is ruled out.

Evaluation

Early Detection of Tuberculosis

This questionnaire gives guidance in identifying individuals who meet OSHA's definition of "suspected infectious tuberculosis" so that appropriate controls can be initiated.

The questionnaire has two parts: (1) reviewing the individual's TB history and (2) assessing current symptoms.

INSTRUCTIONS:

- Record each answer with a check mark
- Add your comments as the evaluator at the bottom of the page.

- Institute the facility's exposure control measures outlined in the facility's Exposure Control Plan, Respiratory Protection and Medical Surveillance Program and refer the individual for further evaluation if the individual has:

(1) A persistent cough lasting 3 or more weeks and two or more symptoms of active TB.

(2) Had a positive TB test on mucous that he/she coughed up.

(3) Been told that he/she had TB and was treated, but never finished the medication.

TB HISTORY (Part One)

Have you ever had a positive TB skin test?  
Yes No Don't Know

Have you ever had an abnormal chest x-ray?  
Yes No Don't Know  
If yes, how long ago?

Have you recently had the mucous you cough up tested for TB?  
Yes No Don't Know  
If yes, were you told it was positive  
Yes No Don't Know

Have you ever been told you have Infectious Tuberculous?  
Yes No Don't Know  
If yes, how long ago?

Have you ever been treated with medication for Infectious TB?  
Yes No Don't Know  
If yes, how many medications?  
One Two Over Two  
Are you still taking TB medicine?  
Yes No

Did you take all the TB medicine until the health care professional told you that you were finished?  
Yes No

Do you live with or have you been in close contact with someone who was recently diagnosed with TB? (e.g. shelter roommate, close friend, relative)  
Yes No Don't Know

CURRENT SYMPTOMS (Part Two)

Do you have a cough that has lasted longer than three weeks?  
Yes No

Do you cough up blood or mucous?  
Yes No

Have you lost your appetite? Aren't hungry?  
Yes No

Have you lost weight (more than 10 pounds) in the last two months? without trying to?  
Yes No

Do you have night sweats (need to change the sheets or your clothes because they are wet)?  
Yes No

Evaluator Comments:

Exposure Control Methods Implemented?  
Yes No

Referred for Further Evaluation? Yes No

Evaluator's Signature

Date

## Appendix G to § 1910.1035—Smoke-trail Testing Method for Negative Pressure Isolation Rooms or Areas

### A. Test Method Description

The purpose of a negative pressure AFB isolation room or area is to prevent TB droplet nuclei from escaping the isolation room or area and entering adjacent or surrounding spaces (e.g., a corridor). One method to check for negative room pressure is to use smoke-trails to demonstrate that the pressure differential is inducing airflow from the corridor through the crack at the bottom of the door (undercut) and into the isolation room or area. When performing a smoke-trail test, follow these recommendations where applicable:

1. Test only with the isolation room or area door shut. If not equipped with an anteroom, it is assumed that there will be a loss of space pressure control when the isolation or area door is opened and closed. It is not necessary to demonstrate direction of airflow when the door is open.

2. If there is an anteroom, release smoke at the inner door undercut, with both anteroom doors shut.

3. In addition to a pedestrian entry, some isolation rooms or areas are also accessed through a wider wheeled-bed stretcher door. Release smoke at all door entrances to isolation rooms or areas.

4. So that the individual conducting the test does not inadvertently force the smoke into the isolation room or area, hold the smoke bottle/tube parallel to the door so the smoke is released perpendicular to the direction of airflow through the door undercut.

5. Position the smoke bottle/tube tight to the floor, centered in the middle of the door jamb and approximately two inches out in front of the door.

6. Release a puff of smoke and observe the resulting direction of airflow. Repeat the test at least once or until consistent results are obtained.

7. Minimize momentum imparted to the smoke by squeezing the bulb or bottle slowly. This will also help minimize the volume of smoke released.

8. Depending on the velocity of the air through the door undercut, the smoke plume will stay disorganized or it will form a distinct streamline. In either case, the smoke will directionally behave in one of three ways. It will:

- (a) Go through the door undercut into the isolation room or area,

- (b) Remain motionless, or

- (c) Be blown back into the corridor.

Negative pressure requires that the smoke be drawn into the isolation room or area through the door undercut.

9. Release smoke from the corridor side of the door only for occupied AFB isolation rooms or areas. If the room is unoccupied, also release smoke inside the isolation room or area (same position as in Step No. 5) to verify that released smoke remains contained in the isolation room or area (i.e., the smoke serves as a surrogate for TB droplet nuclei).

10. To assist in observing the smoke when photography or videotaping is performed, it is recommended that a dark surface be placed on the floor to maximize the contrast. Be aware that most autofocus cameras cannot focus on smoke.

### B. Testing "As Used" Conditions

Testing of negative pressure AFB isolation rooms or areas requires that the test reflect as-used conditions. As-used means that the isolation room or area shall remain the same during testing conditions as it is when in use for isolation. Consider the following use variables that may affect space pressurization and the performance of the negative pressure AFB isolation room or area:

1. Patient toilet rooms are mechanically exhausted to control odors. The position of the toilet room door may affect the pressure differential between the isolation room or area and the corridor. Smoke-trail tests should be performed both with the toilet room door open and the toilet room door closed. This will not be necessary if the toilet room door is normally closed and controlled to that position by a mechanical door closer.

2. An open window will adversely affect the performance of a negative pressure AFB isolation room or area. If the isolation room or area is equipped with an operable window, perform smoke-trail tests with the window open and the window closed.

3. There may be corridor doors that isolate the respiratory ward or wing from the rest of the facility. These corridor doors are provided in the initial design to facilitate space pressurization schemes and/or building life safety codes. Leaving the corridor doors open to the rest of the facility may cause pressure changes in the corridor (e.g., proximity to an elevator lobby) and affect the performance of the negative

pressure AFB isolation room or area. Perform isolation room or area smoke-trail testing with these corridor doors in their "as-used" position, which is either normally open or normally closed.

4. Isolation rooms or areas may be equipped with auxiliary, fan-powered, recirculating, stand alone HEPA filtration or UV units. These units must be running when smoke-trail tests are performed.

5. Do not restrict corridor foot traffic while performing smoke-trail tests.

6. Negative pressure is accomplished by exhausting more air than is supplied to the isolation room or area. Some HVAC systems employ variable air volume (VAV) supply air and sometimes VAV exhaust air. By varying the supply air delivered to the space to satisfy thermal requirements, these VAV systems can adversely impact the performance of a negative pressure isolation room. If the isolation room or area or the corridor is served by a VAV system, the smoke test should be performed twice. Perform the smoke test with the thermostat set at the desired temperature and again with the thermostat set at a lower or higher temperature, depending upon the season, thus simulating the full volumetric flowrate range of the VAV system serving the area being tested.

### C. Smoke

Most smoke tubes, bottles and sticks use titanium chloride (TiCl<sub>4</sub>) to produce a visible fume. There is no OSHA PEL or ACGIH TLV for this chemical, although it is a recognized inhalation irritant. Health care professionals may be concerned about releasing TiCl<sub>4</sub> around pulmonary patients. The smoke released at the door undercut makes only one pass through the isolation room and is exhausted directly outside. (Isolation room air is typically not "recirculated.")

The CDC in the supplementary information to the 1994 TB Guidelines has indicated that "The concern over the use of smoke is unfounded." (Ex. 4B) Controlled tests by NIOSH have shown that the quantity of smoke released during the test is so minute that it is not measurable in the air. Nonirritating smoke tubes are available and may be utilized.

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