CDC

CENTERS FOR DISEASE CONTROL

NIOSH Recommended Guidelines

for

Personal Respiratory Protection

of Workers in Health-Care Facilities

Potentially Exposed to Tuberculosis

DISCLAIMER

Mention of the name of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health.

This document is in the public domain and may be freely copied or reprinted. Copies of this and other NIOSH documents are available from:

Publications Dissemination, DSDTT
National Institute for Occupational Safety and Health
4676 Columbia Parkway
Cincinnati, Ohio 45226
(513) 533–8287

For information about other occupational safety and health problems, call
1–800–35–NIOSH

Foreword

In the *Occupational Safety and Health Act of 1970* (Public Law 91–596), Congress sought "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." The Act requires that the Director of the National Institute for Occupational Safety and Health (NIOSH) "shall develop criteria . . . which will describe exposure levels . . . at which no worker will suffer impaired health or functional capacities or diminished life expectancy as a result of his [or her] work experience."

Aerosolized droplet nuclei containing tubercle bacilli are a hazard to workers in health-care-facilities, which serve persons with infectious tuberculosis. Any TB infection due to occupational transmission to workers in health-care facilities is unacceptable. Available data are insufficient to fully assess the efficacy and reliability of various procedures currently recommended for health-care facilities to prevent the spread of tuberculosis to health-care-facility workers, patients, and visitors. Recognizing this insufficiency, NIOSH, through these recommended guidelines presents its best judgment regarding effective and reliable personal respiratory protection against aerosolized droplet nuclei when this protection is indicated for health-care-facility workers.

NIOSH is the Federal agency which tests and certifies respirators worn by almost 7 million American workers. It has acquired over two decades of experience in research and evaluation activities related to respirators used in American workplaces. Its conclusions and recommendations are based on broad practical experience in many occupational settings, and on the scientific and technical logic and its mandates as presented in this document.
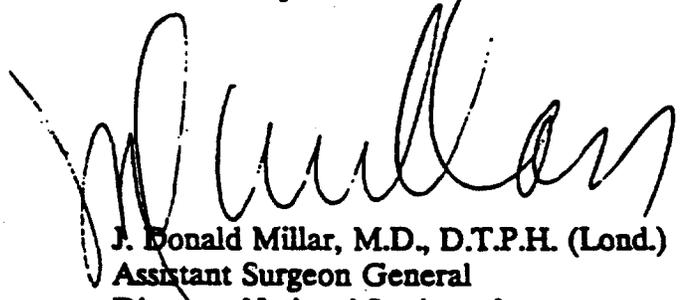
J. Donald Millar, M.D., D.T.P.H. (Lond.)
Assistant Surgeon General
Director, National Institute for
  Occupational Safety and Health
Centers for Disease Control

Summary

These guidelines present the recommendations of the National Institute for Occupational Safety and Health (NIOSH) regarding effective and reliable personal respiratory protection for workers in health-care-facilities who are potentially exposed to tuberculosis. NIOSH concludes that any tuberculosis infection in workers in health-care-facilities due to occupational transmission is unacceptable. With or without clinical disease, tuberculosis infection is a material impairment of these workers' health and establishes a finite probability of developing clinical tuberculosis. Additionally, treatment of tuberculosis-infected workers with isoniazid (INH*) for prophylactic purposes presents these treated workers with another significant risk of undesirable isoniazid-associated health effects (e.g., isoniazid-associated hepatitis).

In any place where workers are potentially exposed to droplet nuclei from a tuberculosis transmitter, the first and highest priority is to reduce the probability of exposure through the use of administrative controls (e.g., rapid identification, early treatment, and isolation of potential tuberculosis transmitters; limiting access to acid-fast bacilli (AFB) isolation rooms; other isolation precautions) implemented in conjunction with engineering controls (e.g., negative-pressure ventilation for AFB isolation rooms to contain any airborne hazard to these rooms; booths, hoods, tents, or other devices for containing droplet nuclei at the source—i.e., a person with infectious pulmonary tuberculosis).

However, it is unlikely that the exposure of workers to droplet nuclei can be completely controlled at the infectious source even where these techniques are implemented to a high degree of efficiency. Therefore, *when confirmed or potential tuberculosis transmitters are present*, use of effective and reliable personal respiratory protection is indicated to assure to the extent possible, the prevention of transmission. This personal respiratory protection is necessary to reduce the risk that workers in health-care-facilities become infected with tuberculosis due to inhalation of droplet nuclei.

So that employers can determine whether effective personal respiratory protection is indicated for health-care-facility workers, NIOSH recommends that *confirmed or potential tuberculosis transmitters* be rapidly identified with an *Admissions Screening Plan* as discussed in section V.B starting on page 37. Then, for a limited range of specific hazardous locations and procedures indicated in Table 3 starting on page 40, when confirmed or potential tuberculosis transmitters are present or potentially present, NIOSH recommends that NIOSH-certified, powered, halfmask respirators equipped with high-efficiency particulate (HEPA) filters always be used by all potentially exposed workers in conjunction with an effective respiratory protection program. For the most hazardous locations and procedures indicated in Table 3 starting on page 40, NIOSH recommends that, at a minimum, NIOSH-certified, positive-pressure, air-line, halfmask respirators always be used in conjunction with an effective respiratory protection program.

Prudent public health practice to fully protect workers dictates that the respirator and respiratory protection program selected should offer the efficacy and reliability of protection equal to or exceeding those recommended in Table 3 starting on page 40. These NIOSH guidelines also include general recommendations for implementing a personal respiratory protection program that is essential for achieving effective and reliable personal respiratory protection when such protection is indicated.

Contents

List of Figures

List of Tables

List of Abbreviations

ACET	Advisory Committee for the Elimination of Tuberculosis
ACIP	Advisory Committee for Immunization Practices
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
AMA	American Medical Association
ANSI	American National Standards Institute
AP	aerosolized pentamidine
CDC	Centers for Disease Control
DFM	dust, fume, and mist [filter]
DM	dust and mist [filter]
HEPA	high-efficiency particulate air [filter]
HIV	human immunodeficiency virus
INH*	CIBA trademark for isoniazid USP
L/min	liters per minute
MDR	multiple-drug resistant
NIOSH	National Institute for Occupational Safety and Health, CDC
OSHA	Occupational Safety and Health Administration, U.S. Department of Labor
PAPR	powered, air-purifying respirator
PR	[disposable] particulate respirator
TB	tuberculosis
UVGI	ultraviolet germicidal irradiation
μm	micrometer or micron

Acknowledgments

I. Introduction

In January 1992, the CDC Tuberculosis Working Group asked that NIOSH "take the lead" in developing guidelines for appropriate personal respiratory protection, i.e. respirators, to protect workers in health-care facilities from occupational transmission of tuberculosis. In addition to consideration of the complex technical issues of respiratory protection which follow, NIOSH personnel also gave careful thought to our understanding of the current epidemiology and control of tuberculosis, to the directives to NIOSH embodied in the *Occupational Safety and Health Act of 1970*, and to the operational philosophy of prudent public health practice.

A.   Current Epidemiology and Control of Tuberculosis—Summary information on the transmission of tuberculosis was reported by CDC in 1991 (*1*):

The number of tuberculosis cases reported to CDC has been increasing since 1988, after a long historic decline. In 1990, 25,701 cases were reported, an increase of 9.4% over the 1989 figure and the largest annual increase since 1952. From 1985 to 1990, reported cases increased by 15.8%. Disproportionately greater increases in reported cases occurred among Hispanics, non-Hispanic blacks, and Asians/Pacific Islanders. In contrast, decreases were observed among non-Hispanic whites and American Indians/Alaskan Natives. By age, the largest increase in reported cases occurred in the 25- to 44-year age group; this increase may be largely attributable to rising numbers of tuberculosis cases among persons with human immunodeficiency virus infection or acquired immunodeficiency syndrome. Notable increases also occurred among children.

Snider and Roper later provided the following caution (2):

Events during the past decade have changed the nature and magnitude of the problem of tuberculosis. Much of what many physicians learned in training about this disease is no longer true. In many respects, tuberculosis has become a new entity.

In 1992, CDC reported that (*3*):

A person who becomes infected with TB bacillus remains infected for years. Usually a person with a healthy immune system does not become ill, but is usually not able to eliminate the infection without taking an antituberculosis drug. This condition is referred to as "latent tuberculosis infection." Persons with latent tuberculosis infection are asymptomatic and cannot spread TB to others. Generally, a positive TB skin test is the only evidence of infection. About 10-15 million persons in this country are infected with *M. tuberculosis*.

According to the American Medical Association, about 70% of infectious tuberculosis cases occur among racial and ethnic minorities, and (*4*):

About 10% of infected persons will develop active tuberculosis at some time in their lives; approximately 5% will develop active disease within the first two years. In the absence of treatment, case fatality is about 50% in five years. ... Patients with drug susceptible strains of tuberculosis can be successfully treated with a three-drug regimen of INH [isoniazid], RIF [rifampin], and PZA [pyrazinamide] given for six months with a 95% cure rate, as previously discussed.

Difficulties have arisen in ensuring a continuing supply of antituberculosis drugs in the United States due to uncertain supplies of isoniazid and other drugs (*2,5*).

Recently, multiple-drug-resistant tuberculosis (MDR-TB) has become a serious concern (*4,6*). *Multiple-drug-resistant* is defined as resistance to two or more primary drugs used in this country for the treatment of tuberculosis (currently isoniazid, rifampin, pyrazinamide, streptomycin, and ethambutol). In a recent survey in New York City, 33% of tuberculosis cases had organisms resistant to at least one drug, and 19% had organisms resistant to both isoniazid (INH[*]) and rifampin, the two most effective drugs available for treating tuberculosis. When organisms are resistant to both INH and rifampin, the course of treatment increases from 6 months to 18-24 months, and the cure rate decreases from about 95% to 60% or less.

Against this background of increasing numbers of tuberculosis cases and increasing numbers of multiple-drug-resistant cases, CDC has reported a serious new phenomenon: outbreaks

of MDR-TB in institutional settings. From 1990 through early 1992, in collaboration with state and local health departments, CDC investigated numerous outbreaks of MDR-TB in hospitals and correctional facilities in Florida and New York (*7,8,9*). To date, these outbreaks have included over 200 tuberculosis cases. Virtually all of these cases have had organisms resistant to both INH and rifampin, and some have had organisms resistant to up to seven antituberculosis drugs. Most of the patients in these outbreaks were infected with HIV. Mortality among patients with MDR-TB in these outbreaks has been very high, ranging from 72 to 89%, and the median interval between diagnosis and death has been very short, from 4 to 16 weeks.

In addition to hospitalized patients and inmates, occupational transmission of MDR-TB to health-care-facility workers and prison guards has been documented. At least nine of these workers have developed clinically active MDR-TB, and five of them have died. Of the eight health-care-facility workers who developed clinically active MDR-TB, five were known to be infected with HIV (*8*).

The continuing occupational hazard of tuberculosis infection in health-care-facilities in conjunction with the continuing outbreaks of tuberculosis in health-care-facility workers led NIOSH to reexamine the role of personal respiratory protection in preventing occupational transmission of tuberculosis infection in health-care settings. There is a paucity of data from well-designed studies regarding both the efficacy and reliability[1] of precautions such as administrative controls, ventilation systems, and particulate respirators (PRs) that are currently recommended (*10*). Regarding the efficacy of ventilation and respirators currently recommended, the following report was given in a summary of a January 1992 conference (*11*):

Data are urgently needed to assess the efficacy of the various isolation procedures currently recommended in facilities. The effectiveness and relative importance of ventilation, ultraviolet lights, particulate respirators, and

---

1. *Reliability* is the probability that an individual wearer will receive adequate protection against airborne tuberculosis transmission over the reasonably-anticipated "life span" of the "protection system" (e.g., days, weeks, months, years of wearing respirators) during which the personal protection must be relied upon under conditions of use that can be reasonably anticipated (e.g., training, fitting, use, and maintenance).

isolation booths must be determined. In the absence of definitive data, "best judgment" recommendations should be developed, perhaps with assessment of the category of proof (strength of evidence) of efficacy, as in the current CDC guidelines for infection control and isolation (*12*).

CDC recently concluded that (*3*):

The efficacy of various technologies for preventing TB transmission (e.g., general and local ventilation, UVGI, and personal protective equipment) has not been adequately evaluated.

B. *The Mandates to NIOSH in the Occupational Safety and Health Act of 1970*—The *Occupational Safety and Health Act of 1970* established the right to safe and healthful working conditions for every working man and woman, and the obligations to provide work and a workplace which are "free of recognized hazards." In its opening paragraphs Congress declared its purpose in passing the Act to be (*13*):

. . . to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources— . . .

In Section 20 of the Act, *Research and Related Activities*, which defines the responsibilities of NIOSH, the Act requires that the Director of NIOSH (*13*):

. . . on the basis of such research, demonstrations, and experiments, and any other information available to him, shall develop criteria dealing with toxic substances which will describe exposure levels that are safe for various periods of employment . . . exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience. (emphasis added)

This mandate sharply defines the obligation of NIOSH to formulate science-based assessments of risk and preventive recommendations which, if implemented, would assure that no worker develops illness as a consequence of exposure at work. Specifically, as regards the occupational transmission of tuberculosis in health-care facilities, NIOSH interpreted its mandate as recommending, where necessary, the use of personal respiratory protection that would assure that no worker will be infected with tubercle bacillus as a result

of occupational exposure. As applied to tuberculosis, this mandate is especially demanding because there is no consensus among experts as to the number, if any, of droplet nuclei containing tubercle bacilli which can be safely breathed by a susceptible worker. Hence, to assure that "no worker will suffer" occupational infection with tubercle bacillus requires the formulation of recommendations which, if implemented, would reduce to the minimum the probability of air contaminated with droplet nuclei being shared between a person with infectious tuberculosis and a worker. The recommendations in this document represent the approach to prevention which most nearly enables NIOSH to meet the directives explicit in the *Occupational Safety and Health Act of 1970*.

C. The Principle of Public Health Prudence—Traditionally, in addition to careful adherence to its mandates in the *Occupational Safety and Health Act of 1970*, NIOSH has developed its recommendations for prevention in accord with an operational philosophy which may be called "the principle of public health prudence." Loosely stated, this principle holds that "when faced with uncertainty, it is better to err in favor of human life and health than in favor of any competing value." In the context of NIOSH recommendations for the protection of workers, the principle may be restated as an informal NIOSH operating policy that "faced with scientific uncertainty, if we must err, it will always be on the side of too much protection for the worker rather than too little." This philosophy is supported in a court decision that OSHA and the Nation's courts "cannot let workers suffer while it awaits the Godot of scientific certainty" (*14*).

NIOSH fully accepts that the evidence available is not adequate to confidently assess both the *efficacy and reliability* of various currently recommended procedures for preventing the transmission of tuberculosis in health-care facilities. Given the absence of definitive data, particularly for the particulate respirators (PRs) now recommended for use in health-care facilities, NIOSH has, on the basis of the well-documented mode of airborne transmission of tuberculosis, scientific and technical logic, and broad experience with personal respiratory protection programs in a variety of occupational settings, attempted a "best judgement." This is consistent both with NIOSH's mandates and prudent practice in the workplace.

II. Mode of Airborne Transmission and Potential for Worker Exposure

A. Airborne Transmission of Tubercle Bacilli—When a person with infectious pulmonary tuberculosis coughs, sneezes, or speaks, particles that can carry viable tubercle bacilli (i.e., infectious particles) can be expelled and then become aerosolized as *droplets* (*15,16*). Tuberculosis bacilli are rod-shaped and vary in width from 0.2 to 0.6 μm, and from 0.5 to 4.0 μm in length (*17,18*). Of the aerosolized particles containing tubercle bacilli that are routinely expelled by a patient with infectious tuberculosis, or produced by clinical or laboratory procedures, the largest particles (e.g., exceeding 100 μm) settle onto surfaces and the tuberculosis bacilli, if present, cannot be inhaled (*19*). However, droplets less than about 100 μm evaporate rapidly to form stable *droplet nuclei* in the 1- to 4-μm size range (*19*). This conversion of droplets to droplet nuclei and the relevant size range of the nuclei required for access to the deep pulmonary spaces have explained in detail by Riley and O'Grady (*19*). One study indicated that 30% of the droplet nuclei resulting from coughs were less than 3 μm (*20*).

Droplet nuclei can remain airborne for prolonged periods of time (hours, at least) (*3*), increasing the likelihood that they will be inhaled by another person. Anyone who breathes air that contains these droplet nuclei can become infected with TB (*3*). After inhalation, droplet nuclei are small enough to reach the alveoli deep in the lung, where tuberculous infection is initiated (*17,18*).

Harris and McClement, in the textbook *Infectious Diseases*, summarized the many complex issues that determine risk of tuberculosis infection as follows (*21*):

The risk of airborne transmission is influenced by many factors, such as the rate and the concentration of expelled organisms, the physical state of the airborne discharge, and the volume and the rate of exchange of the air in the physical space into which the bacilli are ejected. However, the most important risk factor is the length of time an individual shares a volume of air with an infectious case of tuberculosis. Thus, intimate, prolonged, or frequent contact, as in the home or work place, provides the greatest risk of transmission.

Thus risk of infection of a susceptible health-care-facility worker is a function of several factors including:

- The *concentration* of droplet nuclei in the workplace air (*10,15,19,22,23,24, 25,26,27,28,29,30*). There appears to be no exposure threshold for tubercle bacilli in droplet nuclei required to produce infection in a susceptible individual (*22,30*). Thus, any concentration of aerosolized droplet nuclei containing tubercle bacilli is assumed to present some risk of infection.

- The *cumulative time* that air containing droplet nuclei is breathed (*15,22,24,28,29,31*).

- The worker's pulmonary *ventilation rate* (*28,29*).

Of these factors, the first two—concentration and cumulative time—are by far the most important and amenable to intervention.

Persons who share the same air with an infectious person for long periods of time are at greatest risk of becoming infected (*32*). This includes persons living in the same household with the infectious person and those who travel in the same vehicle (*32*). Because tuberculosis is transmitted by the airborne route, persons who sleep, live, work, or who are otherwise in contact or share air with an infectious person through a common ventilation system for a prolonged time are "close contacts" at risk of acquiring tuberculosis infection (*33,34*). Recently, CDC noted that (*35*),

Any person who shared the air space with an MDR-TB patient for a relatively prolonged time (e.g., household member, hospital roommate) is at higher risk for infection than those with a brief exposure to an MDR-TB patient, such as a one-time hospital visitor. Exposure of any length in a small, enclosed, poorly ventilated area is more likely to result in transmission than exposure in a large, well-ventilated space. Exposure during cough-inducing procedures (e.g., bronchoscopy, endotracheal intubation, sputum induction, administration of aerosol therapy), which may greatly enhance TB transmission, is also more likely to result in infection.

However, the terms "long periods of time" and "prolonged time" sharing the air exhaled by an infectious person are subjective. There is one report of a 150-minute intubation and bronchoscopy where 10 of 13 susceptible occupants of an intensive care unit became infected (*36*). In another case, 27 new infections resulted among 67 susceptible office workers who were exposed for 160 hours to the air exhaled by an infectious office worker in the same building (*29*). Additionally, Bloom and Murray noted that (*30*):

... epidemiological findings support the likelihood that the majority of patients infected with TB have acquired infection from nonintimate contacts.

B. Health-Care-Facility Workers' Potential for Exposure to Tuberculosis—Clinical procedures that can result in high concentrations of aerosolized droplet nuclei include bronchoscopy, administering aerosolized drug treatments, autopsy, and physical therapies to the chest that induce coughing (*10*). Rapid transmission (e.g., several hours) to health-care-facility workers has been linked to proximity with patients with infectious tuberculosis during use of aerosolized pentamidine (*37*), intubation and suctioning with mechanical ventilation (*38*), prolonged intubation (*39*), bronchoscopy followed by emergency intubation (*40*), open-abscess irrigation (*41*), and autopsy (*42,43*). Other specific clinical or laboratory procedures that produce droplet nuclei include the manipulation of lesions or processing of tissue or secretions containing tuberculosis bacilli.

U.S. Public Health Service guidelines for biosafety in microbiological and biomedical laboratories state in part (*44*):

Mycobacterium tuberculosis and *M. bovis* infections are a proven hazard to laboratory personnel as well as to others who may be exposed to infectious aerosols in the laboratory. . . .

Biosafety Level 3 practices, containment equipment, and facilities . . . are recommended for activities involving the propagation and manipulation of cultures of *M. tuberculosis* or *M. bovis* and for animal studies utilizing nonhuman primates experimentally or naturally infected with *M. tuberculosis* or *M. bovis*.

Health-care-facility workers may receive exposures to droplet nuclei from confirmed or potential tuberculosis transmitters in outpatient clinics, emergency rooms, and similar locations where patients first make contact with health-care facilities and their workers. In most cases, the status of these patients as potential tuberculosis transmitters at this initial point of contact is not known. Workers in correctional facilities, homeless shelters, and other facilities where tuberculosis outbreaks may occur also come into close contact with persons with infectious tuberculosis before their transmitter status is known. When persons suspected of having, or diagnosed with, infectious tuberculosis are isolated, a limited number of health-care-facility workers are required to enter AFB isolation rooms to administer patient care, perform tests and procedures, and engage in other tasks. Persons with infectious tuberculosis may be transported from one isolation room to another through nonisolated areas of the facility. In each of these situations, health-care-facility workers may be exposed to aerosolized droplet nuclei. Hutton and Polder noted (45):

Until recently TB was probably not often transmitted in hospitals; when it was transmitted, it may have gone unrecognized because transmission did not result in rapid development of large clusters of active (and infectious) TB cases among contacts [both patients and HCFWs]. The recent outbreaks suggest that there may have been more of a problem with occult transmission of tuberculosis infection than was appreciated, especially in hospitals in high-incidence areas where there was a lack of TB surveillance among employees.

III. Methods for Worker Protection—Controlling Airborne Transmission of Tuberculosis

A. Previous Recommendations for Personal Respiratory Protection—The existing CDC guidelines include extensive recommendations regarding the use of respirators in certain higher-risk areas for preventing the transmission of tuberculosis in health-care settings (*10*). These recommendations include in part:

[Section II.D.2.c.] *For persons exposed to tuberculosis patients.* Appropriate masks, when worn by health-care providers or other persons who must share air space with a patient who has infectious tuberculosis, may provide additional protection against tuberculosis transmission. Standard surgical masks may not be effective in preventing inhalation of droplet nuclei (*46*), because some are not designed to provide a tight face seal and to filter out particulates in the droplet nucleus size range (1-5 microns). A better alternative is the disposable PR [NIOSH-certified, particulate respirator]. PRs were originally developed for industrial use to protect workers. Although the appearance and comfort of PRs may be similar to that of cup-shaped surgical masks, they provide a better facial fit and better filtration capability. However, the efficacy of PRs in protecting susceptible persons from infection with tuberculosis has not been demonstrated.

A reexamination by NIOSH of the role of personal respiratory protection, especially the particulate respirator, in protecting health-care-facility workers against tuberculosis infection transmitted in health-care settings is presented in the next section.

B. The "Hierarchy of Controls"—Prudent occupational health practice calls for application of a *hierarchy of controls* to any occupational health hazard (*47,48,49,50*). The control hierarchy is long-standing and has wide-spread acceptance in the occupational-health community because it is based on broad practical experience, and scientific and technical logic (*51*).

NIOSH has supported the necessity of an ordered approach to evaluating a series or combination of effective control strategies to protect workers (*47*). The Institute has recommended the following essential characteristics of specific control solutions (*47*):

- The levels of protection afforded workers must be reliable, consistent, and adequate.

- The efficacy of the protection for each individual worker must be determinable during use throughout the life span of the system.

- The solution must minimize dependence on human intervention for its efficacy so as to increase its reliability.

- The solution must consider all routes of entry into worker's bodies and should not exacerbate existing health or safety problems or create additional problems of its own.

The fundamental strength of the control hierarchy is that it minimizes the likelihood that prevention will "break down" to the extent that results in a hazardous exposure to workers. The control hierarchy for a recognized hazardous source proceeds as follows:

1. Under ordinary circumstances, the most effective and reliable control method is *substitution of a less hazardous substance* or source of exposure for the more hazardous one. Obviously, when the source of a hazardous exposure is a person with infectious tuberculosis, "substitution" as a potential control method is not possible.

2. The next most effective approach is to *prevent or contain hazardous emissions at their source.* In the health-care setting, this is best implemented through administrative controls (e.g., rapid identification, early treatment, and isolation of potential tuberculosis transmitters; limiting worker access to acid-fast bacilli (AFB) isolation rooms; other isolation precautions). Other administrative controls might include providing necessary services and procedures (e.g., portable X-ray units) in the room of a confirmed or potential tuberculosis transmitter rather than moving the infectious person to the service. Additionally, engineering controls should be used (e.g., negative-pressure ventilation for AFB isolation rooms to contain any airborne hazard to these rooms; booths, hoods, tents, or other devices for containing droplet nuclei at the source—i.e., a person with infectious pulmonary tuberculosis).

As a type of source control, it has been recommended that persons with infectious tuberculosis cover their noses or mouths when sneezing or coughing and wear surgical masks (*15,52*). As stated in 1990, both techniques are intended to serve as methods to control the infectious-source (*10*):

A simple but important source-control technique is for infectious patients to cover all coughs and sneezes with a tissue, thus containing most liquid drops and droplets before evaporation can occur [53]. A patient's use of a properly fitted surgical mask or disposable, valveless particulate respirator (PR) (see section II.D.2.c) also may reduce the spread of infectious particles. However, since the device would need to be worn constantly for the protection of others, it would be practical in only very limited circumstances (e.g., when a patient is being transported within a medical facility or between facilities).

Numerous potential limitations of these two techniques must be recognized. Neither the efficacy nor reliability of either technique has been adequately evaluated in clinical or laboratory studies.

Masking of patients is only partially effective as was noted in this caution given in 1982 (*15*):

Masking a coughing patient when someone enters his room may reduce the addition of bacilli to the air; this will not completely eliminate the hazard of transmission, however, since the room air would already be contaminated if the patient had been coughing without covering his mouth.

Because both techniques are heavily dependent on patient behavior, the reliability of both methods and the efficacy of mouth-covering are likely to be highly variable.

With regard to the efficacy of patient masking, a patient's expired airflow takes the path of least resistance, resulting in marginal leakage outward past a mask's face seal. Such airflow patterns deflect at least some of the contagious expired air rather than filtering all of the expired air with its droplet-nuclei load (*46,54*).

With regard to face-seal leakage of particulate respirators (PRs), respirator specialists, manufacturers, and OSHA consider this class of respirators to permit up to 10% (*55,56*) to

20% (*57,58*) inward face-seal leakage even after passing a fit test performed by a qualified individual. Existing standard performance tests for surgical masks have not addressed either inward or outward face-seal leakage (*59*). The inward face-seal leakage for these masks is assumed to be higher than 10% to 20% if the masks are not properly fitted to the wearer's face, tested for an adequate fit by a qualified individual, and then fit checked by the wearer every time these masks are donned. It is reasonable to expect at least as much for outward leakage from a masked patient.

As discussed in section IV.G starting on page 27, surgical masks and NIOSH-certified PRs cannot be reliably fit checked by their wearer before every respirator use to assure a tight face seal. Thus the amount of reduction in droplet nuclei exhaled by a masked patient is unknown. In summary, some trapping of exhaled aerosols will occur in a mask covering a patient's nose and mouth, but the extent of trapping is unknown. Correspondingly, potentially hazardous leakage will inevitably occur past a patient's mask, but the amount of leakage is also unknown.

3. Next in the hierarchy of controls are *engineering controls* to interrupt the pathway of hazardous emissions from the source to the worker(s) (e.g., use of negative-pressure atmospheres and other special ventilation requirements for private isolation rooms to contain the droplet nuclei in the confines of these rooms). This is the rationale for *isolation precautions* in hospitals (*52*). Under certain circumstances, engineering controls may be neither feasible, effective, reliable, or applicable. In such cases, changes in or implementation of work practices or schedules, hazard training programs, and other administrative modifications may reduce the risk of exposure (e.g., minimizing the time a worker is in a room occupied by a potential transmitter).

4. The last, and generally least reliable control measure is to establish barriers between the worker and the hazardous work environment (e.g., personal protection equipment such as appropriate respirators used by workers in conjunction with a comprehensive personal respiratory protection program).

For some infectious diseases, the barrier of immunity can be erected through vaccination of susceptible persons. Vaccination against tuberculosis using BCG vaccine has not been recommended for health-care workers or other adults at high risk for acquiring tuberculosis infection (*60*). The AMA has reported that even should BCG vaccine be recommended for certain health-care workers, "the latter should be aware that the vaccine may not afford significant protection against tuberculosis" (*4*).

NIOSH strongly supports the concept of a hierarchy of controls, which is the foundation of current practice for preventing exposures to hazards in the workplace. Substitution, administrative controls and work practices, and engineering controls because of their greater reliability should receive the highest priority. However, when the effectiveness and reliability of other control measures are not known, cannot completely control the hazard, or cannot be assured under all conditions that can be reasonably anticipated, personal respiratory protection is an essential addition to the armamentarium of control. This is why surgical masks for patient-care personnel have been traditionally indicated for infectious diseases such as Lassa fever, Marburg virus disease, smallpox, and tuberculosis in combination with special-ventilation private rooms (*52*). The purpose of masks for patient-care personnel have been explained as follows (*52*):

In general, masks are recommended to prevent transmission of infectious agents through the air. Masks protect the wearer from inhaling 1) large-particle aerosols (droplets) that are transmitted by close contact and generally travel only short distances (about 3 feet) and 2) small-particle aerosols (droplet nuclei) that remain suspended in the air and thus travel longer distances. . . . If the infection is transmitted over longer distances by air, we recommend masks for all persons entering the room.

At the present time, the exposure of workers to aerosolized TB droplet nuclei cannot be completely controlled at the infectious source nor is it plausible that exposures can be completely prevented by interrupting the pathway of contagious emissions between a person with infectious tuberculosis and workers nearby in the same room. Also at present, it appears impossible to determine the quantitative efficacy and reliability of each available control method. Hence it is impossible to assure that health-care-facility workers will not

be exposed to some aerosolized droplet nuclei at certain locations and during certain procedures. If an infectious person is there, the risk of infection is assumed to exist.

Therefore, for a limited range of locations and procedures, the full hierarchy of controls is necessary. For tuberculosis, these measures include the use of *effective* and *reliable* personal respiratory protection in addition to the administrative and engineering controls. *Respirators can never be considered an adequate substitute for administrative and engineering controls.* These NIOSH guidelines for the selection and use of respirators assume that all indicated administrative and engineering isolation precautions have been rigorously implemented as a prerequisite.

IV. Considerations in the Selection of Respirators

A. Nature of the Hazard to Workers—In considering appropriate personal respiratory protection for health-care-facility workers potentially exposed to tuberculosis, NIOSH considered multiple issues pertaining to the hazard presented to these workers by exposure to aerosolized droplet nuclei in the workplace. These issues included, but were not limited to, the following:

1. The risks of acquiring and medical consequences due to tuberculosis infection (e.g., risk of developing clinical tuberculosis) (e.g., *61,62*).

2. The efficacy, benefits, and risks of chemoprophylaxis with isoniazid of those infected with tuberculosis (e.g., illness due to INH*-induced hepatitis, death from hepatitis) (e.g., *61,62,63,64,65,66,67*).

3. The risks and medical consequences of developing active tuberculosis (e.g., risk of death due to tuberculosis in treated and untreated infected persons, risk of transmitting tuberculosis to co-workers, family members, patients or clients, and the general public) (e.g., *61,62*).

4. The nature of transmission and the relative risk of transmission due to the aerosolization of droplet nuclei from transmitters with differing generation rates of infectious tuberculosis particles. These were appraised for transmitters at varying locations and undergoing varying procedures in health-care facilities (e.g., *22,19,23,24,25,26,28,29,39,68*).

5. The inherent practical limitations of personal respiratory protection programs, admission screening plans, tuberculosis skin-test surveillance programs, and infection-control programs (e.g., *61,66,69,70,71,72,73,74*).

After considering these issues, it was concluded that any tuberculosis infection in a health-care-facility worker[1] due to occupational transmission should be considered unacceptable. Infection of health-care-facility workers with tuberculosis, whether with or without clinical disease, constitutes a preventable impairment of the health of these workers. Additionally, chemoprophylaxis of tuberculosis-infected workers with isoniazid (INH*) poses further significant risks due to isoniazid-related hepatitis and other potential side effects.

The rationale for isoniazid chemoprophylaxis for both those infected and not infected with tuberculosis is to reduce the probability that infected persons will develop active tuberculosis (*75,76*):

When taken as prescribed, isoniazid preventive therapy is highly effective in preventing latent tuberculous infection from progressing to clinically apparent disease. In controlled trials conducted by the Public Health Service in ordinary clinical and public health settings, isoniazid preventive therapy reduced the incidence of disease by 54%–88%. The main reason for the variation in efficacy appears to have been the amount of medication actually taken during the year in which isoniazid was prescribed.

Others have described the limitations of isoniazid prophylaxis as follows (*64*):

Aside from toxicity, which is infrequent but potentially serious, the inconvenience and the lack of motivation for an apparently healthy person to accept long-term medication [6 to 12 months] pose formidable obstacles to preventive therapy programs. . . .

Preventive therapy is inefficient. Among newly infected persons, only about 10% will develop disease during a lifetime, but there is currently no reliable way to distinguish the 10% who will develop disease from the 90% who will not. Thus, 10 or more persons must be given preventive therapy to prevent one future case of tuberculosis.

---

1. The term *health-care-facility workers* refers to all persons working in a health-care setting—including physicians, nurses, aides, and persons not directly involved in patient care (e.g., dietary, housekeeping, maintenance, clerical, and janitorial staff, and volunteers) (*1*).

If isoniazid chemoprophylaxis reduces the incidence of clinical disease by only 54%–88% (*76*), then 11 to 18 persons must be given isoniazid to prevent one future case of active tuberculosis.

In 1992, Snider and Caras reviewed the most serious hazard of isoniazid chemoprophylaxis, death from isoniazid-associated hepatitis (*62*):

Despite the limitations of this survey, we believe the following tentative conclusions are warranted: (1) As suggested by Dash and colleagues, deaths due to INH-associated hepatitis are probably less frequent now than in the early 1970s, but they are still occurring. Efforts to carefully select and monitor patients on INH preventive therapy [prophylaxis] must be continued; (2) Women may be at increased risk of death from INH-associated hepatitis. Therefore, women taking INH should be carefully monitored for hepatotoxicity and preventive therapy recommendations for women should be reconsidered; (3) As suggested by Franks and colleagues, the postpartum period may represent a period when women are especially vulnerable to INH hepatotoxicity; it may be prudent to avoid INH during the postpartum period or at least to monitor postpartum women more carefully; (4) Additional research is needed to identify groups at risk of death from INH-associated hepatitis, to quantify this risk in relative and/or absolute terms, and to identify cofactors that may influence the risk; (5) Better surveillance for INH-associated hepatitis death is warranted.

NIOSH concludes that any use of isoniazid chemoprophylaxis as a substitute for implementing all administrative, engineering, and personal respiratory protection controls indicated for protecting workers in a health-care facility from infection with tuberculosis transmitted in the facility is inconsistent with the rights of workers and obligations of employers established by the *Occupational Safety and Health Act of 1970*.

B. Potential Respirator Leakage—NIOSH evaluated the levels of overall efficacy and reliability of personal respiratory protection offered by different types of NIOSH-certified respirators that might be suitable for personal respiratory protection against aerosolized droplet nuclei (*57,77,78,79,80*). This evaluation focused on two drawbacks that characterize all air-purifying masks equipped with particulate filters—face-seal leakage and filter leakage.

C. Hazardous Face-Seal Leakage—A proper seal between a respirator's sealing surface and a wearer's face is absolutely essential for effective and reliable performance of any respirator with negative pressure inside the facepiece. It is much less critical, but still important, for a positive-pressure respirator. Hazardous face-seal leakage can result from factors such as incorrect facepiece size or shape, incorrect or defective facepiece sealing-lip, beard growth on a wearer, perspiration or facial oils that can result in facepiece slippage, user failure to use all the headstraps, incorrect positioning of a facepiece on a wearer's face, incorrect headstrap tension or position, improper mask maintenance, and mask damage.

To assure an adequate seal, quantitative *fit tests* must be performed periodically and accurately to detect face-seal leakage. Fit tests help ensure that a respirator can provide adequate protection on each wearer and that it is fitted properly to each wearer's face. However, fit tests can detect only the hazardous face-seal leakage that exists at the time of the fit testing. Also, fit tests do not detect hazardous leakage through the filter.

An additional benefit of quantitative fit tests is that the screening cutoff value in these fit tests can be adjusted to assure very low face-seal leakage considerably less than 2% (*81,82*). For example, when quantitatively fit testing, NIOSH uses a screening value of 0.2% leakage for the non-powered operational mode of powered, HEPA-filter, halfmask respirators to assure less than 2% leakage in the powered mode of these respirators.

Because point-of-use factors can create a considerable risk of undetected hazardous leakage past a face seal when a respirator is worn in a hazardous environment, each wearer must have the capability of effectively and reliably fit checking his or her respirator for proper fit before every respirator use. This is the purpose of *fit checks* that must be performed by users each time they don their respirator. The rationale for and the essential nature of both *fit tests* and *fit checks* are summarized in Table 1 on page 20.

Table 1—Requirements for and Essential Roles of Fit Tests and Fit Checks

1—A qualified representative of an employer must decide for which workers personal respiratory protection is indicated using the guidance given in Table 3 starting on page 40.

2—A qualified representative of the employer must identify the "best-fitting" make and size respirator from several different brands and sizes (generally three different sizes are necessary for each brand of respirator). This selection should be done using quantitative fit test(s) (QNFT). Powered masks should be tested and selected while operating in the nonpowered mode.

3—A qualified representative of an employer must then accurately fit-test screen, with the same QNFT from step #2, the face-seal protection afforded to each prospective wearer by the face seal of the respirator identified in the previous element as "best fitting." This screening must accurately detect ("diagnose") those respirator-wearer combinations that will not yield substantial protection on the prospective wearers. Powered respirators should be tested and selected while operating in the nonpowered mode. No filter testing is performed, since it is reliably assumed that the HEPA filters to be worn on the facepieces will have essentially zero leakage. The qualified representative of the employer must also periodically retest the fit of each assigned respirator on its wearer with the QNFT.

4—A qualified representative of an employer then provides and assigns a respirator make and size to those prospective wearers that passed the preceding QNFT screening.

5—Each worker must then (1) decide to wear their respirator, (2) take action to don their respirator, and (3) must properly adjust their assigned respirator on their head and face before each and every entry into any location or before performing any procedure as indicated in Table 3 starting on page 40.

6—Each worker must then perform an accurate fit check at the point of use before each use of their assigned respirator. Fit checks are very simple tests compared to the QNFT performed by a qualified person in steps #2 and #3. The fit check must be done to identify ("diagnose") those respirator "fittings" (respirator facepiece position and headstrap adjustments) not providing substantial protection due to point-of-use factors that are preventing a proper fit (e.g., incorrect respirator position on the user's face, incorrect headstrap tension, incorrect headstrap position on and behind the user's head, user failure to use all the headstraps, changes in a user's facial surface such as facial stubble and perspiration, respirator damage, improper respirator maintenance, or beard stubble).

7—Each worker seeking personal protection must properly wear their assigned respirator in any location or before performing any procedure indicated in Table 3 starting on page 40. They must not wear their respirator when conditions prevent a proper seal of the facepiece to the wearers skin. For respirator-related causes (e.g., respirator malfunction, detection of room-air leakage at their face seal into the respirator), they must (1) decide to leave the location or procedure and then (2) take action and leave.

With regard to hazardous face-seal leakage, *all non-powered* filter masks (e.g., surgical masks and disposable PRs including disposable HEPA-filter respirators) have an inherent deficiency that markedly reduces the level and reliability of personal protection these devices can deliver even when correctly used under ideal conditions. During each inhalation by a wearer, a negative pressure (relative to the workplace air) is created inside the facepiece of this type of respirator. Due to this negative pressure, air containing aerosolized droplet nuclei can take a path of least resistance into the respirator—through leaks at the face-seal interface—thus avoiding the higher-resistance filter material. Additionally, the filter material creates a resistance to the wearer's breathing, which results in physical discomfort, perceptible increases in the work of breathing, and impaired verbal and nonverbal communications (*83*).

In contrast to non-powered filter respirators, *powered* respirators (with HEPA filters) have a design advantage that markedly increases the level and reliability of personal respiratory protection these respirators can deliver under real-world conditions. A powered filter respirator produces a *positive pressure* inside the facepiece under most conditions of use. These respirators deliver a forced airstream to the facepiece using a battery-powered blower. The blower forcibly draws ambient air through HEPA filters, then delivers the filtered air to the facepiece. This air is blown into the facepiece at volumetric flow rates ranging from 115 to 170 L/min (4.1 to 6.0 cubic feet per minute). These flow rates exceed the vast majority of inhalation flow rates expected in workers needing personal protection against droplet nuclei. The small positive pressure inside the facepiece reduces face-seal leakage to very low levels, particularly during the relatively low inhalation rates expected in health-care settings. NIOSH conservatively estimates that these respirators have less than 2% face-seal leakage under routine conditions (*57*). Thus, a powered filter respirator offers substantially higher and more reliable levels of personal respiratory protection than any non-powered filter mask can provide. Examples of this respirator type are given in Figures 1 and 2 on pages 34 and 35.

D. Hazardous Leakage Through Filters—Aerosol leakage through filter media is dependent on at least five types of independent variables (*84*):

- The leakage function for each make and model filter.

- The size distribution of the aerosol.

- The linear velocity through the filtering material, which is a function of the total filtering area and the volumetric flow rate through the filter(s).

- The filter loading (i.e., amount of contaminant deposited on the filter).

- Any electrostatic charges on the filter and on the aerosol.

Respirator filter media other than HEPA filters (e.g., surgical masks, dust and mist filters, or fume filters) have widely varying efficiencies against aerosols less than about 2 to 4 μm (*85,86,87,88*). Only HEPA filters are certified to provide to provide the highest possible efficacy against aerosols smaller than 2 to 4 μm. For HEPA respirator filters, the NIOSH certification performance standard requires these filters be at least 99.97% efficient (i.e., leakage must be less than or equal to 0.03%) against the most filter-penetrating aerosol size (approximately 0.3 μm) (*80*). NIOSH certifications for dust and mist filters, and fume filters, do not permit their use for protection against highly toxic substances (i.e., those substances with exposure limits less than 50 micrograms per cubic meter) (*80*). In contrast, HEPA filters have been previously recommended for general ventilation air that is recirculated from the rooms of known or potential tuberculosis transmitters (*15*) and general-use areas in health-care facilities (*10*).

When HEPA filters are used on an air-purifying respirator, filter efficiency can be reliably assumed to be effectively 100% and hazardous *filter leakage* is not a consideration. Hence, for all HEPA-filter respirators, the potential for inward hazardous leakage of droplet nuclei

is essentially that which occurs at a mask's face seal. In marked contrast, with both surgical masks and NIOSH-certified, disposable, particulate-filter respirators (PRs), one must accept the likelihood of some hazardous leakage through the filter that adds to the hazardous leakage at the face seal.

E. Powered, HEPA-Filter Halfmask and Positive-Pressure, Air-Line, Halfmask Respirators—Available NIOSH-certified, powered, HEPA-filter respirators can supply a constant flow of HEPA-purified air under positive pressure for a period of 8 hours with a fully-charged battery pack. This type of filter respirator is also known by the general term *powered, air-purifying respirator* or PAPR. The specific type of PAPR discussed in these recommendations can be referred to as a "halfmask HEPA PAPR." Two examples of this respirator type are shown in Figures 1 and 2 on pages 34 and 35. NIOSH conservatively estimates that these respirators have less than 2% face-seal leakage under routine conditions (57).

The tight-fitting, elastomeric facepieces and breathing-hose assemblies of these respirators are small and relatively lightweight. The total weight of these devices can go to 5 to 6 pounds, most of which is in the belt-mounted battery, blower, and HEPA-filters assembly. These respirators are designed for continuous use in temperatures ranging from 40°F to 120°F.

The forced, HEPA-filtered airstream flowing into the facepiece of a powered HEPA-filter respirator offers the advantage of a cooling effect in conditions of warm temperatures (this can be a disadvantage for use in cold temperatures). More important, because minimal inhalation effort is needed by the wearer to draw air across the HEPA filters, breathing in a powered respirator is substantially more comfortable than in a non-powered filter respirator (e.g., NIOSH-certified, dust, fume, and mist (DFM) filter respirators).

In use against non-biological aerosols, HEPA filters are routinely replaced only when: (A) airborne materials load them to a point that the flow to the facepiece is not adequate to provide positive pressure or (B) physical damage occurs to a filter. However, in health-care

settings as compared to the dusty industrial environments for which these respirators were originally produced, there should be minimal "loading-size particulates" in the air. Thus, in theory, the HEPA respirator filters could provide a useful life of weeks to months. These respirator filters would normally have to be replaced on about the same frequency as the HEPA filters in the ventilation systems. Before each use, the outside of each HEPA filter should be inspected for physical damage. Biological contamination of HEPA respirator filters should not be a concern, since once any bioaerosols impact on the filter media they are not readily reaerosolized.

Positive-pressure, air-line, halfmask respirators are recommended in Table 3 starting on page 40 as the minimal acceptable devices for a limited number of procedures where the potential for aerosolization of droplet nuclei containing tubercle bacilli is *high* (e.g., bronchoscopy). These devices are also referred to as *pressure-demand, air-line, halfmask respirators*. An example of this respirator type is given in Figure 3 on page 36. NIOSH conservatively estimates that these respirators have less than 2% face-seal leakage under routine conditions (*57*). Additionally, the protective reliability of these respirators is substantially higher than that of powered, HEPA-filter, halfmask respirators because these devices can deliver a higher air flow to a facepiece at a higher positive pressure. Additionally, these respirators do not depend on a battery-powered blower to force clean air into their facepiece. Since no filters are used with these respirators, there is no potential for hazardous filter leakage through the rare occurrence of a damaged or improperly manufactured filters.

Table 2 starting on page 29 summarizes the substantial differences in protection between those respirators recommended by NIOSH and those respirators which have previously been used for protection of workers in health-care-facilities with potential exposures to tuberculosis.

F. Practical Disadvantages of the Recommended Respirators—NIOSH recognizes that the respirators discussed in the preceding section IV.F have some practical disadvantages when compared to the disposable particulate respirators discussed in the next section (IV.G starting on page 27). Due to the use of *powered* air forced into their facepieces, these devices generate some background noise and impair voice communication to some degree, and affect a wearer's range of motion. Also, initially these respirators may present an "intimidating" appearance to patients accustomed to the surgical masks currently used in health-care facilities. These characteristics may affect patient care.

Other drawbacks of powered HEPA-filter respirators include the fact that the battery assembly must be recharged for at least 8 hours after each 8 hours of use. However, this problem can be minimized by purchasing multiple battery packs, dual-rate chargers, and establishing a charging station near the locations and procedures that require respirator usage. Additionally, several types of periodic maintenance are required for a powered respirator. The elastomeric facepieces must be periodically cleaned and disinfected, since these facepieces are not discarded after each use. However, extra halfmask facepieces (available in up to two halfmask models, three facial sizes, two types of elastomeric materials, and two headband types) can be purchased at less than $20 each for assignment to individual workers. Thus, one blower-filter unit can be used for numerous workers at different times. It is not necessary to purchase one complete respirator for each health-care-facility worker.

Also, the breathing hose and facepiece assembly must be periodically inspected for damage or malfunction. The blower must be inspected for adequate delivery of air to the facepiece. Other possible disadvantages are the weight and encumbrance of the battery, blower, and filter assembly, which must be worn on a belt at waist level with a 30-inch-long, corrugated breathing tube connected to the facepiece.

Positive-pressure (a.k.a. pressure-demand), air-line, halfmask respirators require an air supply from an uncontaminated compressed-air source as stipulated by OSHA (*89*). The

air must conform to at least Grade D of ANSI Standard Z86.1. For mobile use of these respirators, the air supply can come from a large laboratory-type cylinder (up to about 4 hours of use) or a much smaller, lighter, 45-cubic-foot cylinder (up to about 30 minutes of use). The latter cylinder is less than 2 feet long and about 8 inches in diameter.

However, any disadvantages of the respirators recommended in these guidelines should be evaluated in the context of the aggregate of other isolation precautions already accepted and in use for potential tuberculosis transmitters. The disadvantages cited must be balanced against the hazard of tuberculosis infection that tuberculosis transmitters pose to health-care-facility workers. The medical community has consistently proved willing to accept the burdens of isolation precautions previously recommended for tuberculosis to assure protection of patients and health-care workers.

It has been argued that hospital personnel will refuse to wear the respirators recommended in these guidelines. This attitude is not a new problem in health-care. Other well-established isolation precautions in health-care settings were initially viewed as inconvenient, burdensome, and deleterious to good patient care. Garner and Simmons have addressed this issue as follows (52):

All personnel—physicians, nurses, technicians, students, and others—are responsible for complying with isolation precautions and for tactfully calling observed infractions to the attention of offenders. Physicians should observe the proper isolation precautions at all times; they must teach by example. The responsibilities of hospital personnel for carrying out isolation precautions cannot be effectively dictated but must arise from a personal sense of responsibility.

In order to provide adequate motivation for respirator wear when it is indicated, personnel must be fully informed regarding the specific risks of tuberculosis infection for which personal respiratory protection is indicated. As noted in section V.D.3 starting on page 43, respirator wearers must receive training in the reasons for the need for wearing their respirator and the potential risks of not doing so. This training and written material would include a full disclosure of the nature, extent, and hazards of tuberculosis infection including

a description of specific risks to each exposed individual due to infection, any subsequent treatment with isoniazid, and the possibility of active disease. Necessary topics are detailed in section V.D.3 starting on page 43. This training must generate a personal sense of responsibility for respirator donning when its use is indicated.

G. *Surgical Masks and Other Disposable Particulate Respirators—*As noted, NIOSH has reexamined the hazards of aerosolized droplet nuclei containing tubercle bacilli and the role, reliability, and efficacy of various personal respiratory protective devices to protect health-care-facility workers against transmission of airborne tuberculosis. Based upon this reexamination, NIOSH concluded that negative-pressure, non-elastomeric, cup-shaped, disposable, particulate-filter respirators (PRs) without HEPA filters (e.g., surgical masks not certified by NIOSH; NIOSH-certified dust and mist filters; NIOSH-certified dust, fume, and mist filters) cannot be relied upon to protect workers exposed to infectious tuberculosis. These devices include those negative-pressure, non-elastomeric, cup-shaped, disposable masks that consist partly or entirely of filter media integrated into the facepiece. That is, certain "maintenance-free" masks with filtering facepieces for which it is difficult, if not impossible, for a wearer to cover the entire filter-surface area, but not cover the face seal between the respirator and the wearer's face.

This conclusion is based on a body of data indicating that these cup-shaped, disposable masks cannot provide effective and reliable personal respiratory protection due to: (1) unreliable face-seal efficacy, (2) inevitable and dangerous face-seal leakage, and (3) potentially excessive filter leakage (*46,59,90,91,92,93*).

Face-seal leakage has long been recognized by respirator specialists as compromising adequate personal protection from any air-purifying respirator, particularly negative-pressure halfmask respirators (*55,94,95*). As noted, existing standard performance tests for surgical-masks have not addressed either face-seal leakage or the effects that prolonged use might have on this leakage (*59*).

Respirator specialists, manufacturers, and OSHA recognize that cup-shaped, disposable masks have up to 10% (*55,56*) to 20% (*57,58*) face-seal leakage even after passing a fit test performed by a qualified individual. This inevitable leakage past face seals results from inherent limitations in the design and construction of these masks. This amount of leakage is unacceptable for effective and reliable respiratory protection against aerosolized droplet nuclei.

What is more relevant, the face-seal leakage for cup-shaped, disposable masks can be considerably higher than 10% to 20% if these masks are not properly fitted to each wearer's face, fit tested by a qualified individual, and then fit checked by each wearer before each respirator use. Both fit testing and fit checking are essential elements in any effective and reliable personal respiratory protection program (*55,57,89*) as summarized in Table 1 on page 20. At this time there are no NIOSH-recommended qualitative or quantitative fit tests for these masks (*81,82*). Cup-shaped, disposable masks cannot be reliably fit checked be wearers (*58*). Therefore, the efficacy and reliability of the face seals on cup-shaped, disposable masks are undependable because there are no proven reliable fit tests nor reliable fit checks. Such devices cannot be relied upon to assure protection of workers against exposure to aerosolized droplet nuclei containing tubercle bacilli.

Another major problem that can contribute to hazardous face-seal leakage of cup-shaped, disposable masks is that in almost all cases these masks are available in only one size. This contrasts with the elastomeric facepieces used for powered, HEPA-filter, halfmask respirators and positive-pressure, air-line, halfmask respirators, which are generally available in up to three different sizes to fit small, medium, and large facial sizes. The single size in which cup-shaped, disposable masks are available tends to produce higher leakage for wearers with small face sizes (e.g., women, Hispanics, Asians) (*96*).

Table 2 starting on page 29 summarizes the substantial differences in protection efficacy and reliability between three categories of respirators, which have been considered for protection of health-care-facility workers potentially exposed to tuberculosis.

Table 2—Summary Comparison of Three Respirator Categories Evaluated for Protection of Health-Care-Facility Workers Potentially Exposed to Tuberculosis

CONSIDERATION	Surgical Masks Not Certified by NIOSH as Dust and Mist Masks	Cup-Shaped, Disposable-Mask, Particulate Respirators (PRs) Certified by NIOSH	Powered, HEPA-Filter, Halfmask Respirators and Positive-Pressure, Air-Line, Halfmask Respirators Certified by NIOSH
EFFICACY OF PROTECTION Face-Seal Leakage	Under optimal use conditions, up to 10% to 20% face-seal leakage is likely for any respirable aerosol (i.e., less than 10 micrometers aerodynamic diameter). Considerably more than 10% to 20% face-seal leakage is possible, since these masks cannot be properly fitted to each wearer's face with fit tests and fit checks. Face-seal efficacy with these masks is uncertain, since there are no proven fit tests for them and they cannot be fit checked. Current standard tests for these masks do not address either face-seal leakage or the effect that prolonged use might have on this hazardous leakage. Only one facepiece size is generally available that tends to produce higher leakages on small facial sizes (e.g., women, Hispanics, Asians).	Under optimal use conditions, up to 10% to 20% face-seal leakage is expected for any respirable aerosol (i.e., less than 10 micrometers aerodynamic diameter). Considerably more than 10% to 20% face-seal leakage is possible, since these masks cannot be properly fitted to each wearer's face with fit tests and fit checks. Face-seal efficacy with these masks is uncertain, since there are no proven fit tests for them and they cannot be fit checked. These NIOSH-certified masks are not NIOSH tested for hazardous face-seal leakage during the certification process. Only one facepiece size is generally available that tends to produce higher leakages on small facial sizes (e.g., women, Hispanics, Asians).	Up to 2% seal leakage under routine use conditions for any respirable aerosol (i.e., less than 10 micrometers aerodynamic diameter). Less than 2% seal leakage can be routinely expected, since these respirators can be properly fitted to each wearer's face with fit tests and fit checks. The screening cutoff value in quantitative fit tests can be adjusted to assure very low face-seal leakage considerably less than 2%. Face-seal efficacy with these respirators is predictable, since they can be both fit tested and fit checked. These NIOSH-certified respirators have been NIOSH tested for their face-seal efficacy during the certification process. Up to three halfmask sizes are generally available to fit a wider range of facial sizes including small faces.
Filter Leakage	Filter leakage of 25% to 85% has been reported at 30 L/min over the size range 1 to 5 micrometers aerodynamic diameter. Filter efficacy has not been adequately evaluated against droplet nuclei.	Filter leakage of 0% to 40% has been reported at 30 L/min over the size range 1 to 5 micrometers aerodynamic diameter. Filter efficacy has not been adequately evaluated against droplet nuclei.	HEPA filters are NIOSH-certified to exhibit less than 0.03% filter leakage against any size aerosol. These filters do not need to be tested specifically against droplet nuclei. With air-line respirators, no filter leakage can occur, since no filters are used in these devices.

CONSIDERATION	Surgical Masks Not Certified by NIOSH as Dust and Mist Masks	Cup-Shaped, Disposable-Mask, Particulate Respirators (PRs) Certified by NIOSH	Powered, HEPA-Filter, Halfmask Respirators and Positive-Pressure, Air-Line, Halfmask Respirators Certified by NIOSH
RELIABILITY OF PROTECTION Face-Seal Leakage	Negative-pressure operation markedly decreases the level and reliability of protection delivered by these masks. Users cannot assure themselves that they are receiving adequate protection because there are no proven fit tests for them and they cannot be fit checked by their users. Employers cannot assure that protection is being received by their employees.	Negative-pressure operation markedly decreases the level and reliability of protection delivered by these masks. Users cannot assure themselves that they are receiving adequate protection because there are no proven fit tests for them and they cannot be fit checked by their users. Employers cannot assure that protection is being received by their employees.	Positive-pressure operation markedly increases the level and reliability of protection delivered by these respirators. Users can assure themselves that they are receiving adequate protection because these respirators can be quantitatively fit tested and fit checked by their wearers. Also, users can readily detect whether or not air is being forced into their face-pieces, which indicates protection is being received. Employers can assure that protection is being received by their employees.
Filter Leakage	Filter reliability has not been adequately evaluated against droplet nuclei.	Filter reliability has not been adequately evaluated against droplet nuclei.	HEPA filters are highly reliable against any size aerosol. Filter reliability is not an issue with air-line respirators, since no filters are used.

V. NIOSH Recommendations for Personal Respiratory Protection

A. *Summary of Conclusions and Recommendations—*

- The National Institute for Occupational Safety and Health (NIOSH) concludes that any tuberculosis infection in health-care-facility workers[1] due to occupational transmission is unacceptable. Infection of health-care-facility workers with tuberculosis, whether with or without clinical disease, is a material impairment of these workers' health and establishes a finite probability of subsequently developing clinical tuberculosis. Additionally, treatment of tuberculosis-infected workers with isoniazid (INH*) for chemoprophylactic purposes can present these treated workers with another significant risk of material impairment of their health or functional capacity due to isoniazid-related health effects (e.g., isoniazid-associated hepatitis).

- NIOSH recommends that wherever there exists the potential exposure of workers to droplet nuclei from a tuberculosis transmitter, the first and highest priority is to reduce the probability of exposure through the use of administrative controls (e.g., rapid identification, early treatment, and isolation of potential tuberculosis transmitters; limiting access to acid-fast bacilli (AFB) isolation rooms; other isolation precautions) implemented in conjunction with engineering controls (e.g., negative-pressure ventilation for AFB isolation rooms to contain any hazard to these rooms; booths, hoods, tents, or other devices for containing droplet nuclei at the source—i.e., a person with infectious pulmonary tuberculosis). However, it is unlikely that the exposure of workers to droplet nuclei can be completely controlled at the infectious source even when these techniques are implemented to a high degree of efficiency. Therefore, for a limited range of specific hazardous locations and procedures, when confirmed or potential tuberculosis transmitters are present, use of effective and reliable personal

---

1. The term *health-care-facility workers* refers to all persons working in a health-care setting—including physicians, nurses, aides, and persons not directly involved in patient care (e.g., dietary, housekeeping, maintenance, clerical, and janitorial staff, and volunteers) (*1*).

respiratory protection is indicated to assure, to the extent possible, the prevention of transmission. This personal respiratory protection is necessary to reduce the risk of health-care-facility workers becoming infected with tuberculosis due to their inhalation of droplet nuclei.

- NIOSH concludes that the use of isoniazid chemoprophylaxis as a substitute for primary prevention of occupational transmission through all administrative, engineering, and personal respiratory protection controls is not consistent with the provisions of the *Occupational Safety and Health Act of 1970.*

The following personal respiratory protection recommendations are intended specifically for a limited range of specific hazardous locations and procedures in health-care facilities. These locations primarily include rooms or areas where confirmed or potential tuberculosis transmitters are present. These locations also include any clinical and laboratory areas where certain procedures that could produce infectious airborne materials are performed on: (A) confirmed or potential tuberculosis transmitters or (B) tissue or fluids potentially containing tubercle bacilli. Specific examples are given in Table 3 starting on page 40. These NIOSH recommendations represent the Institute's best judgment as to what is necessary to achieve effective and reliable personal respiratory protection against droplet nuclei for workers in settings where this protection is indicated.

- NIOSH recommends that any *confirmed or potential tuberculosis transmitters (10,15)* in health-care facilities be rapidly identified with an *Admissions Screening Plan,* as discussed in section V.B starting on page 37, so that employers can determine whether personal respiratory protection may be indicated for health-care-facility workers.

- NIOSH recommends that, when confirmed or potential tuberculosis transmitters are present or potentially present at hazardous locations and procedures indicated as "medium" in Table 3 starting on page 40, NIOSH-certified, powered, halfmask respirators equipped with high-efficiency particulate (HEPA) filters be used in

conjunction with an effective respiratory protection program (55,57,89). The powered airflow to the halfmask respirator facepiece must exceed 4 cubic feet per minute and 6 cubic feet per minute is recommended. Two examples of this respirator type are given in Figures 1 and 2 on pages 34 and 35.

* NIOSH recommends that, when confirmed or potential tuberculosis transmitters are present at certain other hazardous locations and procedures indicated as "high" in Table 3 starting on page 40, NIOSH-certified, positive-pressure, air-line, halfmask respirators be used in conjunction with an effective respiratory protection program (55,57,89). An example of this respirator type is given in Figure 3 on page 36.

* NIOSH recommends that for all potential exposures to droplet nuclei containing tubercle bacilli, prudent public health practice dictates the use of respirators and a respiratory protection program which offers the highest efficacy and reliability of protection equal to or exceeding that specified in Table 3 starting on page 40.

* NIOSH recommends that any respirator provided to workers in health-care-facilities for personal respiratory protection be used in conjunction with an effective respiratory protection program (55,57,89) so that respirator wearers might receive the maximum personal protection their respirators are capable of providing.

Figure 1—Example A of a NIOSH-Certified, Powered, HEPA-Filter, Halfmask Respirator (MSA Powered, Air-Purifying Respirator, NIOSH approval TC-21C-186).

Figure 2—Example B of a NIOSH-Certified, Powered, HEPA-Filter, Halfmask Respirator (MSA OptimAir 6A, NIOSH approval TC-21C-513).

Figure 3—Example C of a NIOSH-Certified, Positive-Pressure, Air-Line, Halfmask Respirator (MSA Pressure Demand Air-Line Respirator, NIOSH approval TC-19C-158).
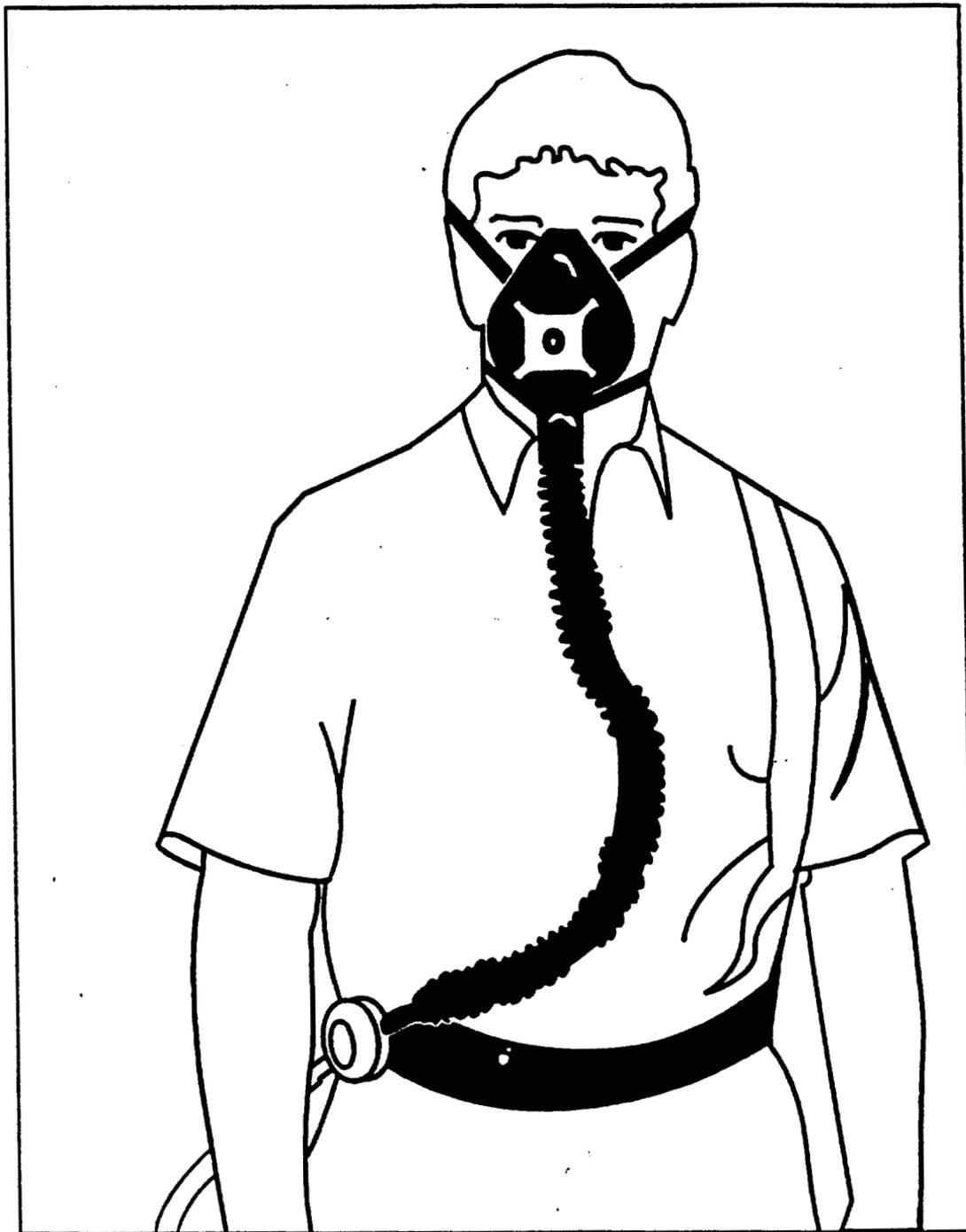
B. Identifying Confirmed or Potential Tuberculosis Transmitters in a Health-Care Facility—Worker protection against tuberculosis infection is critically dependent upon rapid identification of any potential tuberculosis transmitters in a health-care facility. This high-priority identification can be accomplished with an *Admission Screening Plan* (*15*). A qualified infection-control committee in each facility should review information about persons admitted to the facility and develop an *Admission Screening Plan.* The purpose of this Plan is to specify screening criteria for effectively identifying any individual that is a *confirmed or potential tuberculosis transmitter*. CDC has previously given the following guidance regarding diagnosing tuberculosis and determining the infectiousness of a person with active tuberculosis (*10*):

A diagnosis of tuberculosis should be considered for any patient with persistent cough or other symptoms compatible with tuberculosis, such as weight loss, anorexia, or fever. Diagnostic measures for identifying tuberculosis should be instituted for such patients. These measures include history, physical examination, tuberculin skin test, chest radiograph, and microscopic examination and culture of sputum or other appropriate specimens (*16,97*). Other diagnostic methods, such as bronchoscopy or biopsy, may be indicated in some cases (*98,99*). The probability of tuberculosis is increased by finding a positive reaction to a tuberculin skin test or a history of a positive skin test, a history of previous tuberculosis, membership in a group at high risk for tuberculosis (see section V.B), or a history of exposure to tuberculosis. Active tuberculosis is strongly suggested if the diagnostic evaluation reveals AFB in sputum, a chest radiograph is suggestive of tuberculosis, or the person has symptoms highly suggestive of tuberculosis (e.g., productive cough, night sweats, anorexia, and weight loss). Tuberculosis may occur simultaneously with other pulmonary infections, such as PCP. . . .

The infectiousness of a person with tuberculosis correlates with the number of organisms that are expelled into the air, which, in turn, correlates with the following factors: a) anatomic site of disease, b) presence of cough or other forceful expirational maneuvers, c) presence of AFB in the sputum smear, d) willingness or ability of the patient to cover his or her mouth when coughing, e) presence of cavitation on chest radiograph, f) length of time the patient has been on adequate chemotherapy, g) duration of symptoms, and h) administration of procedures that can enhance coughing (e.g., sputum induction).

The most infectious persons are those with pulmonary or laryngeal tuberculosis. Those with extrapulmonary tuberculosis are usually not infectious, with the following exceptions: a) nonpulmonary disease located in the respiratory tract or oral cavity, or b) extrapulmonary disease that includes an open abscess or lesion in which the concentration of organisms is high, especially if drainage from the abscess or lesion is extensive (*100*).

Although the data are limited, findings suggest that tuberculosis patients with acquired immunodeficiency syndrome (AIDS), if smear positive, have infectiousness similar to that of tuberculosis patients without AIDS (CDC/New York City Department of Health, unpublished data).

Infectiousness is greatest among patients who have a productive cough, pulmonary cavitation on chest radiograph, and AFB on sputum smear (*31*). Infection is more likely to result from exposure to a person who has unsuspected pulmonary tuberculosis and who is not receiving antituberculosis therapy or from a person with diagnosed tuberculosis who is not receiving adequate therapy, because of patient noncompliance or the presence of drug-resistant organisms. Administering effective antituberculosis medication has been shown to be strongly associated with a decrease in infectiousness among persons with tuberculosis (*25*). Effective chemotherapy reduces coughing, the amount of sputum, and the number of organisms in the sputum. However, the length of time a patient must be on effective medication before becoming noninfectious varies (*101*); some patients are never infectious; whereas those with unrecognized or inadequately treated drug-resistant disease may remain infectious for weeks or months. Thus, decisions about terminating isolation precautions should be made on a case-by-case basis.

In general, persons suspected of having active tuberculosis and persons with confirmed tuberculosis should be considered infectious if cough is present, if cough-inducing procedures are performed, or if sputum smears are known to contain AFB, and if these patients are not on chemotherapy, have just started chemotherapy, or have a poor clinical or bacteriologic response to chemotherapy. A person with tuberculosis who has been on adequate chemotherapy for at least 2–3 weeks and has had a definite clinical and bacteriological response to therapy (reduction in cough, resolution of fever, and progressively decreasing quantity of bacilli on smear) is probably no longer infectious. Most tuberculosis experts agree that noninfectiousness in pulmonary tuberculosis can be established by finding sputum free of bacilli by smear examination on three consecutive days for a patient on effective chemotherapy. Even after isolation precautions have been discontinued, caution should be exercised when a patient with tuberculosis is placed in a room with another patient, especially if the other patient is immunocompromised.

Other guidance has been given by CDC regarding diagnosing tuberculosis and determining the infectiousness of a person with active tuberculosis, for tuberculosis occurring in correctional institutions (*33*), high-risk populations (*76*), and long-term-care facilities (*34*).

C. Selection of Minimal Acceptable Personal Respiratory Protection—Table 3 starting on page 40 summarizes the types of minimal acceptable personal respiratory protection for health-

care-facility workers potentially exposed to tuberculosis. This table also specifies the conditions, locations, and procedures where personal respiratory protection is indicated.

Table 3—NIOSH Recommendations for Minimal Acceptable Personal Respiratory Protection for Health-Care-Facility Workers Potentially Exposed to Tuberculosis

These recommendations are indicated for workers in areas *where confirmed or potential tuberculosis transmitters are present* (see note 1). These recommendations are also indicated for any clinical and laboratory areas where effective infectious-source controls are not in use and certain procedures that could produce hazardous airborne material are performed on: (A) *confirmed or potential tuberculosis transmitters* or (B) tissue or fluids that could contain tubercle bacilli.

WARNING—These respirators help protect against airborne tuberculosis transmission by reducing the inhaled concentrations. Failure to follow all instructions and limitations on the use of these respirators and/or failure to wear them during all times of exposure can reduce respirator effectiveness and may result in tuberculosis infection and possible death.

No respirator is capable of assuring that all droplet nuclei are prevented from entering the wearer's breathing zone. Misuse of these respirators will increase the risk of inhaling airborne tubercle bacilli and may cause tuberculosis infection and possible death. For this reason, proper training in the use of these respirators is essential in order for the wearer to receive protection (56).

Without an effective respiratory-protection program, respirator wearers are not likely to receive the protection that can be afforded by their respirator, even if it is a correct choice for the situation. As a minimum, compliance with OSHA regulation 29 CFR 1910.134 for occupational respirator use is essential whenever respirators are used by employees, whether required or on a voluntary basis.

Table 3 (continued)—NIOSH Recommendations for Minimal Acceptable Personal Respiratory Protection for Health-Care-Facility Workers Potentially Exposed to Tuberculosis

Potential for Aerosolization of Droplet Nuclei	Locations and Procedures Where Confirmed or Potential Tuberculosis Transmitters Are Present or Potentially Present (see note 1)	Minimal Acceptable Personal Respiratory Protection
High	Administration of aerosolized pentamidine (and other aerosols) Any cough-inducing procedure Autopsy rooms, aerosol-generating procedures (e.g., irrigating, sawing) Bronchoscopy procedures Endotracheal intubation/suctioning procedures Sputum induction	POSITIVE-PRESSURE, AIR-LINE, HALFMASK RESPIRATORS USED IN CONJUNCTION WITH AN EFFECTIVE RESPIRATORY PROTECTION PROGRAM
Medium	AFB isolation rooms Intensive-care units, routine procedures Laboratories (see note 2) Non-cough-inducing procedures Operating rooms	POWERED, HEPA-FILTER, HALFMASK RESPIRATORS USED IN CONJUNCTION WITH AN EFFECTIVE RESPIRATORY PROTECTION PROGRAM
Indeterminant (see note 3)	Admitting areas Emergency rooms (including waiting areas) Hallways Transport of patients Waiting areas (inpatient and outpatient)	*POSSIBILITY OF EXPOSURE* POWERED, HEPA-FILTER, HALFMASK RESPIRATORS USED IN CONJUNCTION WITH AN EFFECTIVE RESPIRATORY PROTECTION PROGRAM - *NO POSSIBILITY OF EXPOSURE* NO RESPIRATOR NEEDED

Note 1—As identified with an **Admission Screening Plan** as discussed in section V.B starting on page 37.

Note 2—Respirators are not indicated when effective infectious-source controls are in use such as given in (*44*).

Note 3—Whether or not there is a risk depends on whether or not there is a possibility of exposure to a person with infectious tuberculosis.

D. Implementing a Personal Respiratory Protection Program—Whenever personal respiratory protection is necessary as an additional isolation precaution for protection of health-care-facility workers potentially exposed to tuberculosis, an effective personal respiratory protection program must be developed, implemented, administered, and periodically reevaluated (55,57,89):

To be effective, any respiratory protection program, must be supervised by a qualified individual who has sufficient knowledge of respiratory protection. When necessary, employers should obtain the required expertise (e.g., professionals such as industrial hygienists, infection control practitioners, or safety specialists who have been specifically trained in personal respiratory protection) to ensure that the personal respiratory protection program is effectively developed, implemented, administered, and periodically reevaluated. The services of a physician are required to conduct the medical surveillance portion of the program.

Information on how to develop and manage a respiratory protection program is available in technical training courses covering the basics of personal respiratory protection, which are offered by organizations such as NIOSH, OSHA, and the American Industrial Hygiene Association. In addition, similar short courses are available from private contractors and universities.

In order to be effective and reliable, any respiratory protection program must contain at least the following eight elements (55,57,89):

1. Standard Operating Procedures: Written standard operating procedures should contain all information needed to maintain an effective respirator program to meet each user's individual requirements. These procedures should be written so as to be useful to those persons responsible for aspects of the respirator program such as, but not limited to: (1) the program administrator, (2) those responsible for fit testing wearers' face seals and training the respirator wearers, (3) respirator-maintenance workers, and (4) the supervisors

responsible for overseeing respirator use in the health-care facility to ensure that respirators are worn when indicated.

2. Medical Surveillance: Health-care-facility workers should not be assigned a task requiring use of respirators unless they are physically able to do the work while wearing the respirator. A physician should determine what health and physical conditions are pertinent for the medical surveillance and periodically review the respirator wearer's medical status.

A physician should classify workers according to their ability to use the necessary respirators. A medical history and at least a limited physical examination are recommended. The medical history and physical examination should emphasize the evaluation of the cardiopulmonary system and should elicit any history of previous respirator use. This history can be an important tool to detect problems that might require further evaluation. The physical examination should seek to detect medical conditions that may be essentially asymptomatic. While chest roentgenograms and/or spirometry may be medically indicated in some determinations of fitness, these need not be routinely performed.

3. Training: Selecting the most protective respirator appropriate for a given hazard is important, but equally important is using the selected device properly each time it is necessary for personal respiratory protection. To help ensure proper use, both supervisors and health-care-facility workers should be trained in selection, use, and maintenance of respirators appropriate for personal protection against airborne tuberculosis. The training program should include instructional material and training covering at least the following elements:

- The reasons why personal respiratory protection is required.

- The nature, extent, and specific hazards of tuberculosis transmission in health-care facilities. The references provided in section IV.A starting on page 16 may aid in the preparation of this material that should include:

— The specific risks, non-medical consequences of acquiring, and medical consequences of acquiring tuberculosis infection (e.g., risk of developing clinical tuberculosis).

— The efficacy, benefits, and specific risks of chemoprophylaxis with isoniazid indicated for those infected with tuberculosis (e.g., illness due to INH*-induced hepatitis and possible death from hepatitis).

— The specific risks and medical consequences of developing clinically active tuberculosis (e.g., risk of death due to tuberculosis in treated and untreated infected persons; illness due to active tuberculosis; risks of transmission to coworkers, family members, patients or clients, and the general public).

— The nature of transmission and the relative risk of transmission (i.e., infectiousness) due to the aerosolization of droplet nuclei from individuals with differing generation rates of infectious tuberculosis particles (i.e., transmitters) at varying locations and undergoing varying procedures in health-care facilities.

— Some of the inherent practical limitations of personal respiratory protection programs, admission screening plans, employee tuberculosis skin-test surveillance programs, and infection-control programs that increase the hazard to health-care-workers due to airborne transmission of tuberculosis in their workplace.

— Information about the risk for life-threatening clinical tuberculosis in persons with immunocompromising conditions.

• An explanation of why engineering controls are not being applied or are not adequate, and of what effort is being made to reduce or eliminate the need for personal respiratory protection.

- An explanation of why a particular type of respirator has been selected and provided for a specific location or procedure.

- An explanation of the operation, and the capabilities and limitations, of the respirator provided.

- Instruction in how the respirator wearer should inspect, don, fit check, and correctly wear their provided respirator.

- An opportunity for each wearer to handle the respirator, learn how to don and wear it properly (i.e., achieve a proper face-seal fit on the wearer's face), check important parts (e.g., battery charge, flow rate, filters, air supply), and wear it in a safe atmosphere.

- An explanation of how the respirator is properly maintained and stored.

- Instruction in how to recognize an inadequately functioning respirator and how to recognize and cope with emergency situations.

4. Face-Seal Fit Testing and Fit Checking: The rationale for and the essential roles of fit tests performed by qualified persons and fit checks performed by respirator wearers before every use are detailed in Table 1 on page 20.

5. Respirator Inspection, Cleaning, Maintenance, and Storage: Scrupulous respirator maintenance should be made an integral part of the overall respirator program. Manufacturers' instructions for inspection, cleaning, and maintenance of respirators should be followed to ensure that the respirator continues to function properly. Wearing poorly maintained or malfunctioning respirators may be more dangerous than not wearing a respirator at all because the worker wearing a defective device will falsely assume that protection is being provided. A proper maintenance program ensures that the worker's

respirator remains as effective as it was when new. All respiratory-protection maintenance programs should include at least the following:

- inspection for physical damage or defects

- replacing and disposing of used filter elements as necessary

- cleaning and disinfecting (as indicated by hospital infection control procedures)

- repair

- proper storage (i.e., clean, disinfected respirators placed in a sealed container and stored in a dry, noncontaminated environment).

6. Surveillance of the Health-Care Facility and Exposures of Workers in Health-Care-Facilities: Because air sampling methods for airborne concentrations of droplet nuclei are not currently available, exposures of health-care-facility workers cannot be quantified. However, efforts should be made to periodically evaluate the work environment for changes in ventilation, isolation procedures, work practices (such as frequency of entering AFB isolation rooms), and other factors that may affect the probability of exposure to droplet nuclei. These assessments must be conducted in addition to the *Admission Screening Plan* discussed in section V.B starting on page 37. Information collected from these surveillance activities should be used to determine if the personal respiratory protection program is effective.

7. Respirator Selection: NIOSH recommends that for all exposures to droplet nuclei, the respirator and respiratory protection program selected should offer efficacy and reliability of protection equal to or exceeding that specified in Table 3 starting on page 40. All such respirators should be NIOSH-certified (*79,80*).

8. Periodic Evaluation of the Personal Respiratory Protection Program: Periodic evaluation of the entire personal respiratory protection program is essential to ensure that health-care-facility workers are being adequately protected. The program should be completely evaluated at least once annually, and both the written operating procedures and program administration should be modified as necessary based on the results. This evaluation should be conducted by a qualified program administrator who has overall responsibility for all aspects of the program.

Frequent evaluation of respirator use will determine whether the correct respirators are being used and worn properly. Examination of respirators in use and in storage will indicate the adequacy of respirator maintenance. Wearers should be consulted periodically about their acceptance of respirators, including any discomfort, resistance to breathing, fatigue, interference with vision and communication, restriction of movement, and any interference with job performance and the wearer's confidence in the respirator's efficacy and reliability.

The results of periodic inspections of respirator use, consultations with wearers, surveillance of work area conditions, and medical surveillance of wearers should be reviewed, studied, and analyzed to evaluate the effectiveness and reliability of the personal respiratory protection program. Evidence of the failure of personal respiratory protection (e.g., tuberculosis skin-test conversions) should be aggressively addressed to determine whether the indicated respirator was used properly, and what remedial action is needed. The results of the program evaluation should be presented in a written report that lists plans to correct failures with the target dates for their implementation.

References

1. Jereb JA, et al. Tuberculosis morbidity in the United States: final data, 1990. In: CDC Surveillance Summaries, December 1991. MMWR 1991; 40(No. SS-3):23-27.

2. Snider DE, Roper WL. The new tuberculosis. N Engl J Med 1992; 326:703-705.

3. CDC. National action plan to combat multidrug-resistant tuberculosis: recommendations of the CDC TB Task Force. MMWR 1992; 41(No. RR-11).

4. American Medical Association. Report 00 of the Board of Trustees (A-92)— Multiple-drug resistant tuberculosis: a multifaceted problem. 1992.

5. Peloquin CA. Shortages of antimycobacterial drugs. N Engl J Med 1992; 326:714.

6. Villarino ME, Dooley SW, Geiter LJ, Castro KG, Snider DE Jr. Management of persons exposed to multidrug-resistant tuberculosis. MMWR 1992; 41(No. RR-11).

7. CDC. Nosocomial transmission of multidrug-resistant TB to health-care workers and HIV-infected patients in an urban hospital—Florida. MMWR 1990; 39:718-722.

8. CDC. Nosocomial transmission of multidrug-resistant tuberculosis among HIV-infected persons—Florida and New York, 1988-1991. MMWR 1991; 40:585-591.

9. CDC. Transmission of multidrug-resistant tuberculosis among immunocompromised persons in a correctional system— New York, 1991. MMWR 1992; 41:507-509.

10. CDC. Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. MMWR 1990; 39(No. RR-17).

11. CDC. Meeting the challenge of multidrug-resistant tuberculosis: summary of a conference. MMWR 1992; 41(No. RR-11).

12. Williams WW. CDC guideline for infection control in hospital personnel. Infect Control 1983; 4(suppl):328-49. Reprinted in NIOSH guidelines for protecting the safety and health of health care workers. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 88-119, September 1988, pp. A8-85 to A8-109.

13. Occupational Safety and Health Act of 1970, Public Law 91-596, December 29, 1970.

14. United Steelworkers v. Marshall. 647 F.2d 1189 (D.C. Cir. 1980).

15. CDC. Prevention of TB transmission in hospitals. Atlanta, GA: U.S. Department of

Health and Human Services, Public Health Service, Centers for Disease Control, Center for Prevention Services, DHHS Publication No. (CDC) 82-8371, October 1982.

16. American Thoracic Society. Diagnostic standards and classification of tuberculosis. Am Rev Respir Dis 1990; 142:725-735.

17. Smith D. Mycobacterium tuberculosis and tuberculosis. In: Joklik WK and Smith DT, eds. Zinsser Microbiology. 15th ed. New York, NY: Ashton-Century-Crofts, 1972: 454.

18. Breed RS, Murray EGD, Smith NR. Bergey's manual of determinative bacteriology. 7th ed. Baltimore, MD: The Williams & Wilkins Company, 1957:701-702.

19. Riley RL, O'Grady F. Airborne infection—transmission and control. New York: Macmillan, 1961.

20. Loudon RG and Roberts RM. Droplet expulsion from the respiratory tract. Am Rev Respir Dis 1967; 95:435-442.

21. Harris HW, McClement JH. Pulmonary tuberculosis. In: Hoeprich PD, ed. Infectious diseases—a modern treatise of infectious processes. 3rd ed. Philadelphia, PA: Harper & Row, 1983:378-404.

22. Nardell EA. Dodging droplet nuclei: reducing the probability of nosocomial tuberculosis transmission in the AIDS era. Am Rev Respir Dis 1990; 142:501-503.

23. Riley RL, . Air hygiene in tuberculosis: quantitative studies of infectivity and control in a pilot ward. Am Rev Tuber 1957; 75:420-31.

24. Riley RL, Mills CC, et al. Aerial dissemination of pulmonary tuberculosis—a two-year study of contagion in a tuberculosis ward. Am J Hyg 1959; 70:185-96.

25. Riley RL, Mills CC, O'Grady F, Sultan LU, Wittstadt F, Shivpuri DN. Infectiousness of air from a tuberculosis ward. Amer Rev Respir Dis 1962; 85:511-25.

26. Houk VN, Baker JH, Sorensen K, et al: The epidemiology of tuberculosis infection in a closed environment. Arch Environ Health 1968; 16:26-35.

27. Johnston RF, Wildrick KH. "State of the art" review. The impact of chemotherapy on the care of patients with tuberculosis. Am Rev Resp Dis 1974; 109:636-664.

28. Riley RL, Nardell EA. Clearing the air—the theory and application of ultraviolet air disinfection. Am Rev Respir Dis 1989; 139:1286-94.

29. Nardell EA, Keegan J, Cheney SA, Etkind SC. Airborne infection—theoretical limits of protection achievable by building ventilation. Am Rev Respir Dis 1991; 144:302-306.

30. Bloom BR, Murray CJL. Tuberculosis: commentary on a reemergent killer. Science 1992; 257:1055-64.

31. American Thoracic Society. Control of tuberculosis. Am Rev Respir Dis 1983; 128:336-342.

32. CDC. Prevention and control of tuberculosis in migrant farm workers. MMWR 1992; 41(No. RR-10).

33. CDC. Prevention and control of tuberculosis in correctional institutions: recommendations of the Advisory Committee for the Elimination of Tuberculosis. MMWR 1989; 38:313-320, 325.

34. CDC. Prevention and control of tuberculosis in facilities providing long-term care to the elderly. MMWR 1990; 39(No. RR-10).

35. CDC. Management of persons exposed to multidrug-resistant tuberculosis. MMWR 1992; 41(No. RR-11).

36. Malasky C, Jordan T, Potulski F, Reichman LB. Occupational tuberculous infections among pulmonary physicians in training. Am Rev Respir Dis 1990:505-507.

37. CDC. *Mycobacterium tuberculosis* transmission in a health clinic: Florida 1988. MMWR 1989; 38:256-64.

38. Haley CE, McDonald RC, Rossi L, et al. Tuberculosis epidemic among hospital personnel. Infect Control Hosp Epidemiol 1989; 10:204-210.

39. Ehrenkranz JN, Kicklighter LJ. Tuberculosis outbreak in a general hospital: evidence for airborne spread of infection. Ann Intern Med 1972; 77:377-82.

40. Catanzaro A. Nosocomial tuberculosis. Am Rev Respir Dis 1982; 125:559-62.

41. Hutton MD, Stead WW, Cauthen GM, et al. Nosocomial transmission of tuberculosis associated with a draining tuberculous abscess. J Infect Dis 1990; 161:286-295.

42. Lundgren R, Norrman E, Asberg I. Tuberculous infection transmitted at autopsy. Tubercle 1987; 68:147-150.

43. Kantor HS, Poblete R, Pusateri SL. Nosocomial transmission of tuberculosis from unsuspected disease. Am J Med 1988; 84:833-838.

44. CDC and NIH. Biosafety in microbiological and biomedical laboratories, 2nd edition. Washington, DC: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and National Institutes of Health, HHS Publication No. 88-8395, May 1988.

45. Hutton MD, Polder JA. Guidelines for preventing tuberculosis transmission in health care settings: What's new? Am J Infec Control 1992; 20:24-26.

46. Pippin DJ, Verderame RA, Weber KK. Efficacy of face masks in preventing inhalation of airborne contaminants. J Oral Maxillofac Surg 1987; 45:319-323.

47. NIOSH. Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration advance notice of proposed rulemaking: June 1983, OSHA Docket No. H-160. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

48. NIOSH. NIOSH comments on the Occupational Safety and Health Administration proposed rule on health standards; methods of compliance: 29 CFR Part 1910, October 2, 1989, OSHA Docket No. H-160. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

49. NIOSH. NIOSH testimony on the Occupational Safety and Health Administration proposed rule on health standards; methods of compliance: 29 CFR Part 1910, May 31, 1990, OSHA Docket No. H-160. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

50. NIOSH. NIOSH post-hearing comments on the Occupational Safety and Health Administration proposed rule on health standards; methods of compliance: 29 CFR Part 1910, October 9, 1990, OSHA Docket No. H-160. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

51. Olishifski JB. Methods of Control. In: Plog BA, ed. Fundamentals of industrial hygiene. 3rd. ed. Chicago, IL: National Safety Council, 1988:457-474.

52. Garner JS, Simmons BP. Guideline for isolation precautions in hospitals. Infect Control 1983; 4(suppl):245-325. Reprinted in NIOSH guidelines for protecting the safety and health of health care workers. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 88-119, September 1988, pp. A8-1 to A8-84.

53. Riley RL. Airborne infection. Am J Med 1974; 57:466-75.

54. Ha'eri GB, Wiley AM. The efficacy of standard surgical face masks: an investigation using "tracer particles." Clin Ortho Rel Res 1980; 148:160-162.

55. ANSI. ANSI Z88.2–1980—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1980.

56. 3M Company. 1991 Respirator selection guide. St. Paul, Minnesota: 3M Occupational Health and Environmental Safety Division, 1991.

57. NIOSH. NIOSH guide to industrial respiratory equipment. Morgantown, WV: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 87-116, January 1991.

58. National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987).

59. Davis WT. Filtration efficiency of surgical face masks: the need for more meaningful standards. Am J Infec Control 1991; 19:16-18.

60. CDC. Use of BCG Vaccines in the control of tuberculosis: a joint statement by the Immunization Practices Advisory Committee and the Advisory Committee for the Elimination of Tuberculosis. MMWR 1988; 37:663-664, 669-675.

61. Greenberg PD, Lax, KG, Schechter, CB. Tuberculosis in house staff—a decision analysis comparing the tuberculin screening strategy with the BCG vaccination. Am Rev Respir Dis 1991; 143:490-495.

62. Snider DE, Caras, GJ. Isoniazid-associated hepatitis deaths: a review of available information. Am Rev Respir Dis 1992; 145:494-497.

63. Kopanoff DE, Snider DE, Caras GJ. Isoniazid-related hepatitis: a US Public Health Service cooperative surveillance study. Am Rev Respir Dis 1978; 117:991-1001.

64. Snider DE, Farer LS. Preventive therapy for tuberculosis infection: an intervention in need of improvement. Am Rev Respir Dis 1984; 130:355-6.

65. Des Prez RM, Heim, CR. Mycobacterium tuberculosis. In: Mandell GL, Douglas RG, Bennett, JE, eds. Principles and practice of infectious diseases. 3rd. ed. New York, NY: Churchill Livingstone, 1990:1877-1905.

66. Moulding TS, Redeker AG, Kanel GC. Twenty isoniazid-associated deaths in one state. Am Rev Respir Dis 1989; 140:700-5.

67. Israel HL, Gottlieb JE, Maddrey WC. Perspective: preventive isoniazid therapy and the liver. Chest 1992; 101:1298-1301.

68. Wells WF. Airborne contagion and air hygiene. Cambridge: Harvard University Press, 1955.

69. Ruben FL, Norden CW, Schuster N. Analysis of a community hospital employee tuberculosis screening program 31 months after its inception. Am Rev Respir Dis 1977; 115:23-28.

70. Vogeler DM, Burke JP. Tuberculosis screening for hospital employees: A five year experience in a large community hospital. Am Rev Respir Dis 1978; 117:227-232.

71. Barrett-Connor E. The epidemiology of tuberculosis in physicians. JAMA 1979; 241:33-38.

72. Geiseler PJ, Nelson KE, Crispen RG. Tuberculosis in physicians: compliance with preventive measures. Am Rev Respir Dis 1987; 135:3-9.

73. Bentley DW. Tuberculosis in long-term care facilities. Infect Control Hospital Epidemiol 1990; 11:42-46.

74. Lin-Greenberg A, Anez T. Delay in respiratory isolation of patients with pulmonary tuberculosis and human immunodeficiency virus infection. Am J Infec Control 1992; 20:16-18.

75. American Thoracic Society and Centers for Disease Control. Treatment of tuberculosis and tuberculosis infection in adults and children. Am Rev Respir Dis 1986; 134:355-63.

76. CDC. Screening for tuberculosis and tuberculosis infection in high-risk populations, and The use of preventive therapy for tuberculosis infection in the United States: recommendations of the Advisory Committee for Elimination of Tuberculosis. MMWR 1990; 39(No. RR-8).

77. Teresinski MF, Cheremisinoff PN. Industrial respiratory protection. Ann Arbor, MI: Ann Arbor Science Publishers, 1983.

78. Rajhans GS, Blackwell, DSL. Practical guide to respirator usage in industry. Boston, MA: Butterworth Publishers, 1985.

79. NIOSH. NIOSH certified equipment list as of December 31, 1991. Morgantown, WV: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 92-101, January 1992.

80. NIOSH. 30 CFR Part 11—respiratory protective devices; tests for permissibility, fees. Code of Federal Regulations. Washington, DC: U.S. Government Printing Office, Office of the Federal Register.

81. NIOSH. Requirements for respirator fit testing in the OSHA lead standard: report submitted to the Occupational Safety and Health Administration, October 1981, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of

Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

82. NIOSH. Supplemental report to OSHA for docket H-049A: evaluation of quantitative and proposed qualitative screening tests for inadequate fit factors of respirator users, October 1982, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

83. Iseman MD. A leap of faith—what can we do to curtain intrainstitutional transmission of tuberculosis? Ann Int Med 1992; 117:251-53.

84. Hyatt EC, et al. Respiratory studies for the National Institute for Occupational Safety and Health—July 1, 1972 through June 3, 1973. Los Alamos, NM: Los Alamos Scientific Laboratory, Progress Report, No. LA-5620-PR, May 1974.

85. Hinds WC and Kraske G. Performance of dust respirators with facial seal leaks: I. Experimental. Am Ind Hyg Assoc J 1987; 48(10):836-841, Figures 5 and 6.

86. Liu BYH and Fardi B. A fundamental study of respiratory air filtration. Final report for NIOSH Grant #R01 OH01485-01A1, University of Minnesota, Particle Technology Laboratory Publication No. 680, Minneapolis, Minnesota, 1988. Chapter 6: Experimental results, p. 250-307.

87. Chen CC, Ruuskanen J, et al. Filter and leak penetration characteristics of a dust and mist filtering facepiece. Am Ind Hyg Assoc J 1990; 51(12):632-639.

88. Chen CC, Lehtimäki M, Willeke K. Aerosol penetration through filtering facepieces and respirator cartridges. Am Ind Hyg Assoc J 1992; 53(9):566-574.

89. OSHA. 29 CFR 1910.134—occupational safety and health standards, personal protective equipment, respiratory protection. Code of Federal Regulations. Washington, DC: U.S. Government Printing Office, Office of the Federal Register.

90. Rogers KB. An investigation into the efficiency of disposable face masks. J Clin Pathol 1980; 33:1086-1091.

91. Cooper DW, Hinds WC, Price JM, Weker RT, Yee HS. Common materials for emergency respiratory protection: leakage tests with a manikin. Am Ind Hyg Assoc J; 44:720-726.

92. Tuomi T. Face seal leakage of half masks and surgical masks. Am Ind Hyg Assoc J 1985; 46:308-312.

93. Chen, C, Willeke, K. Aerosol penetration through surgical masks. Am J Infec Control 1992; 20:177-84.

94. Hyatt EC. Current problems and new developments in respiratory protection. Am Ind Hyg Assoc J 1963; 24:295-304.

95. ANSI. ANSI Z88.2-1969—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1969.

96. Lowry PL, Hesch PR, and Revoir WH. Performance of single-use respirators. Am Ind Hyg Assoc J 1977; 38:462-67.

97. CDC. Tuberculosis and human immunodeficiency virus infection: recommendations of the Advisory Committee for Elimination of Tuberculosis (ACET). MMWR 1989; 38:236-8, 243-50.

98. Willcox PA, Benator SR, Potgieter PD. Use of flexible fiberoptic bronchoscope in diagnosis of sputum-negative pulmonary tuberculosis. Thorax 1982; 37:598-601.

99. Willcox PA, Potgieter PD, Bateman ED, Benator SR. Rapid diagnosis of sputum-negative miliary tuberculosis using the flexible fiberoptic bronchoscope. Thorax 1986; 41:681-4.

100. Hutton MD, Stead WW, Cauthen GM, et al. Nosocomial transmission of tuberculosis associated with a draining tuberculous abscess. J Infect Dis 1990; 161:286-95.

101. Noble RC. Infectiousness of pulmonary tuberculosis after starting chemotherapy: review of the available data on an unresolved question. Am J Infect Control 1981; 9:6-10.

September 21, 1992

Ms. Dorothy L. Strunk
Assistant Secretary for Occupational
  Safety and Health
U.S. Department of Labor
Room South 2315
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Ms. Strunk:

     This is in follow-up to the letter to you dated
September 17, 1992, from Dr. J. Donald Millar, Director,
National Institute for Occupational Safety and Health (NIOSH),
Centers for Disease Control (CDC).

     In that letter Dr. Millar transmitted to you the
"NIOSH Recommended Guidelines for Personal Respiratory Protection
of Workers in Health-Care Facilities Potentially Exposed to
Tuberculosis." In addition Dr. Millar indicated that CDC is
initiating a process to revise the current CDC recommendations
contained in the December 7, 1990, Morbidity and Mortality Weekly
Report entitled "Guidelines for Preventing the Transmission of
Tuberculosis in Health-Care Settings, with Special Focus on
HIV-Related Issues."

     The NIOSH recommended guidelines call for the use of
powered, halfmask respirators equipped with high-efficiency
particulate filters by workers in health-care facilities
potentially exposed to confirmed or potential tuberculosis (TB)
transmitters. Dr. Millar stated in his letter transmitting these
same recommendations to me that the recommendations meet the
NIOSH mandate in the Occupational Safety and Health Act. He
further stated that NIOSH recognizes that there are drawbacks to
using the recommended respirators and that these drawbacks could
form a basis for consideration in developing risk management
options.

     CDC is organizing an open meeting in Atlanta on October 22-23
to bring together experts in the fields of TB prevention and
control, nosocomial infection prevention, biosafety, and
occupational safety and health as well as representatives of
labor, medical, and hospital administration organizations to
assess the need to revise the current CDC guidelines. The
meeting will be announced in the Federal Register. Many leaders
in the field of TB control have expressed to CDC their views that
the current guidelines with respect to this issue are appropriate
and do not need to be revised. Because of the complexity of

these issues and the public health importance of this problem, I have asked the Co-chairs of the National Multi-Drug Resistant Tuberculosis Task Force--Dr. Alan R. Hinman, Director, National Center for Prevention Services, CDC, and Dr. James M. Hughes, Director, National Center for Infectious Diseases, CDC--to coordinate this meeting, with Dr. Millar's assistance.

I cannot emphasize too strongly that CDC considers personal protective equipment to be only one element in the management of TB risk to the health-care worker. Obviously, the disadvantages in patient care due to the use of the recommended equipment must be carefully considered. Some of these and other yet unrecognized drawbacks could become impediments to overall national efforts to prevent and control TB. These issues will be explored in the October meeting.

I invite representatives of the Occupational Safety and Health Administration (OSHA) to participate in the meeting. Please identify an appropriate contact person on your staff, and I will ask Drs. Hinman and Hughes to provide additional information to that person regarding the agenda and logistics of the meeting.

I recommend that OSHA consider the results of this meeting in determining actions to take relative to implementing the NIOSH guidelines. If you concur with this process, then I suggest you share that information with the OSHA regional offices and state offices so that they can benefit from these further deliberations.

We look forward to working closely with OSHA to ensure timely implementation of optimal prevention strategies to address this important public health problem in a consistent and effective manner.

Sincerely,
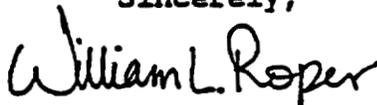
William L. Roper, M.D., M.P.H
Director

cc:
Dr. Alan R. Hinman
Dr. James M. Hughes
Dr. J. Donald Millar

DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

                                                        National Institute for
                                                          Occupational Safety and Health
                                                        Centers for Disease Control
                                                        Atlanta GA 30333

                                                        SEP 1 7 1992

Dorothy L. Strunk
Assistant Secretary for Occupational
  Safety and Health
U. S. Department of Labor
Room South 2315
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Dear. Ms. Strunk:

This is in response to your request of August 19, to provide the Occupational Safety and
Health Administration as soon as possible the NIOSH Recommended Guidelines for
Personal Respiratory Protection of Workers in Health-Care Facilities Potentially
Exposed to Tuberculosis. Enclosed is a copy of the requested document.

This recommendation meets our mandate in the Occupational Safety and Health Act
[Section 20(a)(3)] to "develop criteria . . . which will describe exposure levels that are
safe for various periods of employment, including but not limited to exposure levels at
which no employee will suffer impaired health or functional capacities or diminished life
expectancy as a result of his work experience" (emphasis added).

This recommendation was also transmitted to the Director of CDC by the enclosed cover
memorandum dated September 14, 1992. You will note that this cover memorandum
states that a number of issues and considerations pertaining to feasibility, user
acceptability, and resource implications, have not been addressed in this NIOSH
assessment.

It is my understanding that Dr. William L. Roper has initiated a process to revise the
current CDC recommendations contained in the December 7, 1990, MMWR entitled,
"Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings,
With Special Focus on HIV-related Issues." The enclosed NIOSH assessment will be
taken into consideration by CDC as it revises the 1990 CDC recommendation. I will
keep you updated on this process as it unfolds.

If you have any questions about our recommendations or need further information, please do not hesitate to contact me.

Sincerely,

J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

Memorandum

Date　·　September 14, 1992

From　　Director, NIOSH (D36)

Subject　　NIOSH Recommended Guidelines for Personal Respiratory Protection of Health-Care-Facility Workers Potentially Exposed to Tuberculosis

To

William L. Roper, M.D.
Director, CDC (D14)

By a process of extensive deliberations over many months, and using our legal mandates as guidance, we have assessed the risks of occupational transmission of tuberculosis and developed a NIOSH recommendation for the use of personal respiratory protection to protect health-care workers against these hazards (attached as "NIOSH Recommended Guidelines for Personal Respiratory Protection of Health-Care-Facility Workers Potentially Exposed to Tuberculosis").

This recommendation meets our mandate in the Occupational Safety and Health (OSH) Act [Section 20(a)(3)] to "develop criteria . . . which will describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience" (emphasis added).

The use of the respirators described in our recommendations, i.e., the powered, air-purifying halfmask respirator, or the positive-pressure air-line halfmask respirator, will assure protection against tuberculosis consistent with the criteria specified in the quote from the OSH Act. Respirators with negative pressure inside the mask, such as disposable particulate respirators as recommended in the 1990 CDC guidelines, might more easily achieve widespread acceptance, but will not assure a sufficient level of protection because of inward leakage of potentially contaminated air.

Under conditions of optimal use, particulate respirators may allow up to 20 percent leakage around the face seal. Further, the cup-shaped disposable particulate respirators cannot be reliably fit-checked by wearers with each donning. Thus, the actual protection provided by such devices for any individual is unpredictable. The powered, air-purifying respirators recommended by NIOSH can be fit-tested and fit-checked by their wearers, and reliably prevent at least 98 percent of face seal leakage if properly worn and maintained.

We recognize that safety of workers as defined by the OSH Act is not the only issue that CDC must consider in developing guidelines for managing the risks caused by the spread of tuberculosis. We recognize that powered, air-purifying and air-line (supplied-air) respirators involve additional noise, impairment of voice communication, limitation of range of motion, additional costs, and an appearance that might intimidate patients accustomed to seeing health-care workers wearing the currently used, typical surgical mask. We also recognize that these characteristics may result in disadvantages in patient care, possibly leading to a failure by health-care providers to adhere consistently to the recommended protection. These drawbacks could form a basis for criteria in considering several risk management options in the revised CDC guidelines.

Full implementation of other aspects of the 1990 CDC guidelines, including early case identification, isolation, ventilation, and work practices, in the absence of universally effective personal respiratory protection, will reduce risks, although not to nil.

We conclude that the respirators recommended by NIOSH against the hazard of infectious tuberculosis constitute the reliable personal respiratory protection that meets the statutory NIOSH risk assessment mandate.
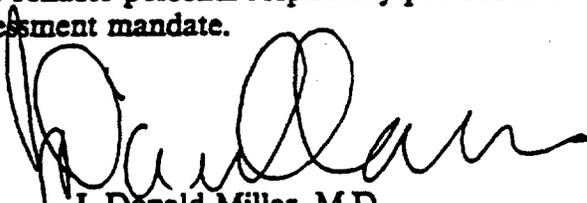
J. Donald Millar, M.D.
Assistant Surgeon General

Attachment