94-290

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NEOTERIK HEALTH TECHNOLOGIES, INC.

July 20, 1994

NIOSH Docket Office
Robert A Taft Laboratories, Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

Gentlemen:

We are a small business manufacturing, among other items, respirators which are NIOSH approved. We are submitting this comment on 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule.

These comments refer to Section 84.180 (26855 and 26884).

This section concerns the Filter Type Identification. The proposal is that filters are to be labelled as Type A/S, Type A/L&S, Type B/S, Type B/L&S, Type C, Type C/L&S. It is explained on 26855 that, "This information would be necessary to allow the user to make an informed decision on selecting the appropriate respiratory protection.

We have two comments:

1. The Proposed Rules do not indicate how the user is to make this decision. What basis is he to use? Guidance will be urgently needed.

   It would appear that a user could reasonably decide when to use a Type A filter, because this would be a continuation of the existing Hepa filters. But when can he use a Type B or a Type C?

   For example, existing dust/mist filters have a limitation from NIOSH which says :

   "Approved for respiratory protection against dusts and mist having a TWA-PEL not less than 0.05 mg/cu.m. or 2 mppcf."

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Similar statements currently exist for other particulate filters, relating the Approval to a TWA-PEL level.

The Part 84 Proposal does not include such a relationship. There is no answer for the following practical questions:

What TLV or TWA-PEL can I use my Type B filter to protect against?

This material has a TWA of 0.1 mg/cu.m. Can I use a Type B? Can I use a Type C? Must I use a Type A?

The OSHA standard for respiratory protection for coke oven emissions (1910.1029) allows the use of a PAPR with a particulate filter for dust and mist. Do I use a Type B? Do I use a Type C? Must I use Type A?

These questions are typical of those that users will ask. The Proposed Rules do not answer these, and they should.

2. There is a danger that users will misinterpret the efficiency information on the labels. The efficiency level may be confused with the total protection provided by the respirator.

For example, disposable respirators have been established to have a face-leakage factor of up to 20% even after they have been fitted by a knowledgeable person.

> Suppose a user has a disposable respirator with a label stating that it is a Type C filter, 95% efficiency. Suppose the ambient concentration of dust is 100 mg/cu.m. This user might interpret the label as meaning that a wearer will breathe only 5 mg/cu.m, and then might base his decision to use this disposable respirator on that exposure. In fact, the wearer is likely to get this 5 mg/cu.m. which comes through the filter, and a much greater amount, up to 20 mg/cu.m, which comes around the mask into the breathing zone, adding up to 25 mg/cu.m.

In the above example, then, a disposable respirator with statement on the NIOSH label which says it has an efficiency of 95%, does not have the expected Protection Factor of 20, but has a Protection Factor of only 4.

This information needs to be made clear on the Approval label , or there will be mis-use of respirators in use.

KV Vaughan

Kenneth V. Vaughan
President

NEOTERIK

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July 20, 1994 /B

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Gentlemen:

We are a small business manufacturing, among other items, respirators which are NIOSH approved. We are submitting this comment on 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule.

These comments relate to certain parts of the Summary (26850), Supplementary Information: Paperwork Reduction Act (26852) and the Executive Order 12866 and Regulatory Flexibility Act (26859). The parts referenced are those that refer to the CDC Notice of Comment Period on Draft Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, published in the Federal Register on Tuesday October 12, 1993 (52810).

NIOSH refers to this Draft from CDC in the Proposal 42 CFR Park 84 as follows:

On Page 26850 (Part 84):

> "The certification of air purification respirators under these proposed requirements would also enable respirator users to select from a broader range of certified respirators that meet the current performance criteria recommended by CDC for respiratory devices used in health-care settings for protection against Mycobacteruim tuberculosis."

And also on Page 26852 (Part 84):

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"This (CDC) draft enumerates four performance criteria that CDC has determined are necessary for respiratory protective devices used in health-care setting for protection against TB. The only current certified air-purifying respirator class that meets all the respiratory protection performance criteria in the CDC draft is a respirator with a Hepa filter. However, all six classes of air purifying particulate respirators to be certified under the provisions of the near particulate filter tests would meet or exceed the performance recommendations contained in the CDC document."

And also on Page 26859 (Part 84):

"The classes of particulate filter-respirators certified under this rule will meet or exceed the CDC recommendations . . . create options for the choice of respirators that adhere to CDC recommendations at a reduced expense."

We are opposed to these comments, and we believe they are out of place and inappropriate in CFR 84. Our reasons are as follows:

1. The CDC Draft is, indeed, only a draft. It was published in the Federal Register for Comment. Our information from CDC is that the final version is not yet ready. It may, or may not, contain the same criteria for respirators. We certainly submitted comments opposing these criteria, and supporting the more protective recommendations made by NIOSH in September 1992. NIOSH should not assume that the CDC criteria will be adopted nor should NIOSH place such an obvious value on them. It is ironic indeed that NIOSH should be promoting a clear reduction in respiratory protection from their own recommendations as an industrial benefit because cheaper respirators can be used!

2. We are including as Appendix 1, the CDC Recommendations for Respiratory Protection for M. tuberculosis, 52821 of the FR, October 12, 1993. We are also including as Appendix 2, the "NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis", dated September 4, 1992. It appears from the statement in Part 84 on Page 26850, 26852, and 26859 (as included above) that NIOSH is not supporting their own Recommendations of September, 1992. Their carefully researched and presented work has been dumped for no reason, apparently, other than that another set of criteria was forthcoming from CDC, and CDC is the parent agency of NIOSH. We hope that this reporting relationship is not, in fact, what has caused NIOSH to abandon their scientific Recommendations. It is hard to imagine what else would cause NIOSH to reverse their

professional judgements so radically, and to now tacitly support other criteria which will clearly result in much reduced protection for those workers involved.

Consider these statements from the NIOSH Guidelines of September 1992:

(a) In the Foreward, NIOSH states:

"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."

Despite this, NIOSH is apparently accepting criteria put forward by another Agency, even though these criteria result in much lower protection for the workers involved.

(b) On Page 5, NIOSH states:

"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 faces with uncertainty, it is better to err in favor of human life and health then 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"

Despite this, NIOSH is apparently accepting criteria put forward by another Agency, even though these criteria result in much lower protection for the workers involved.

(c) On Page 12, NIOSH states:

"With regard to face-seal leakage of (disposable) particulate respirators (PRs), respirator specialists, manufacturers, and OSHA consider this class of respirators to permit up to . . . 20% inward face seal leakage even after pushing a fit test performed by a qualified individual.

This finding demonstrates that disposable respirators will not satisfy even the much reduced criteria put forward by CDC, because even CDC wants a face-seal leakage of no more than 10% for most workers. Despite this, NIOSH still states in Part 84 that all respirators, including disposables, will meet the CDC requirements, and by so doing, accept a much lower protective level for workers that NIOSH themselves determined.

3. We are opposed to the statement that all classes of particulate respirators certifed under this NIOSH proposal will be suitable for protecting Health Care Workers (HCWs) from exposure to TB for the following reasons:

a) NEED FOR PROTECTION OF HCWs FROM TB:

We agree that there is an urgent need to update and replace the previously published CDC guidelines for the personal respiratory protection of HCWs exposed to TB transmission. Clearly, TB infection is a real impairment of the health of HCWs and is associated with a well established risk of developing clinical TB. This, in itself, justifies an effective respiratory protection program, because it is established that the infection is transmitted by airborne particulates. These circumstances are now aggravated by the appearance of MDR-TB, and by the fact that some HCWs with HIV infection may be exposed to TB with deadly consequences. All these consideration together virtually demand an effective respiratory protection program.

b) The "NIOSH RECOMMENDED GUIDELINES FOR PERSONAL RESPIRATORY PROTECTION OF WORKER IN HEALTH-CARE FACILITIES POTENTIALLY EXPOSED TO TUBERCULOSIS" HAVE BEEN SET ASIDE BY THE CDC WITHOUT TECHNICAL OR NON-TECHNICAL JUSTIFICATION, RESULTING IN CDC'S RECOMMENDATION BEING MUCH LESS PROTECTIVE THAN NIOSH'S RECOMMENDATION.

On September 14, 1992, NIOSH issued their Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to TB. NIOSH has a well earned reputation as an authority, having acquired over twenty years of experience in research and evaluation activities related to respirators used in American workplaces. Its conclusions and recommendations are, among other things, based on broad practical experience in many occupational settings, on well-presented scientific and technical logic, and on its mandate from Congress. In other areas of occupational exposure, the recommendations from NIOSH are given well-deserved importance and any departure from their recommendations are well explained. The CDC Draft Guidelines of October 12, 1993 are markedly different in their respiratory protection recommendations from those presented by NIOSH on September 14, 1992. There are no explanations in the CDC recommendations for this departure.

This table presents some of the differences between the CDC Guidelines and the NIOSH Guidelines:

Respiratory Protection of HCWs against TB

	NIOSH Guidelines (Sept. 14, 1992)	CDC Guidelines (Oct. 12, 1993)
(i)	Able to filter at least 99.97% of particles 1 micron in size when unloaded	Lowers the requirement to 95% of particles 1 micron in size when unloaded
(ii)	Able to obtain a face-seal leakage of no more than 2% for most workers	Lowers the requirement to a face-seal leakage of no more than 10% for most workers
(iii)	Does not allow the use of disposable, cup-shaped masks with Hepa filter approvals	Lowers the requirements to allow the use of disposable, cup-shaped masks with Hepa filter approvals
(iv)	Does not allow the use of disposable, cup-shaped mask	Lowers the requirement to allow the use of certain disposable, cup-shaped masks, despite there being a risk of face-seal leakage considerably more than 20%

(v)	Does not allow the use of disposable cup-shaped masks.	Lowers the requirement to allow the use of certain disposable, cup-shaped masks ven though they are not tested for hazardous face-seal leakage during the NIOSH certification process

These differences are each very important. In every case, the CDC Guidelines result in a protection level which is less than the NIOSH Guidelines. Taken together, the differences create a CDC recommendation for respiratory protection which is significantly less than that recommended by NIOSH.

This marked, deliberate reduction is recommended without any accompanying justification. There is no scientific or technical logic presented. There is no reference to practical experience of successful protection in HCWs or other settings. The CDC departures from the NIOSH recommendation are not supported evidentially, and are not supported by good industrial hygiene practice. CDC should justify its selection of less protective devices, or they should endorse and include the NIOSH recommendations.

(c) THE CDC GUIDELINES DO NOT SPECIFY THAT HCWs INVOLVED IN HIGH RISK PROCEDURES MUST HAVE VERY EFFECTIVE RESPIRATORS.

The CDC Guidelines recommend a Risk Assessment logic, which analyses an area or occupational group and classifies it as "low risk", "intermediate risk", or "high risk" based upon the outcome. Then, the CDC Guidelines indicate that a different level of respiratory protection be used according to this classification of areas or occupation groups. In other words, the CDC Guidelines recommend that respirators be selected and used in response to the rate of TB infection experienced by HCWs. This approach to selecting and using respirators is not acceptable. Respirators must be selected on the basis of the hazards to which the HCWs are exposed, and not on any other basis.

Two analogies might illustrate the point:

Consider an area in which workers are using grinding wheels to finish metal parts. Industrial hygiene practice recognizes that there is a real risk of eye injuries. If the hazard cannot be eliminated, workers will be given eye protection. The Risk Assessment logic in the CDC Guidelines would result in a different approach. First, the records would be examined to check how many eye injuries had occurred. If this number is not significantly greater than other areas, the workers would not be given eye protection. When the inevitable eye injuries take place, the statistical record would reflect the need for eye protection, and it would be issued. Then, again, when the record shows later that there are no longer any eye injuries, the eye protection will be withdrawn in accordance with the CDC-type decision logic because it will be deemed (incorrectly!) as unnecessary. Such an approach is obviously not providing the necessary protection for the workers.

Consider an area in which workers are spray painting with isocyanate paints. Industrial hygiene practice recognizes that there is a real risk of damage to the workers respiratory systems, up to and including death. If the hazard cannot be eliminated, workers will be given very effective respiratory protection. The Risk Assessment logic in the CDC Guidelines would result in a different approach. First, the records would be examined to check how many workers had suffered respiratory system damage. If this number is not significantly greater than other areas, the workers would not be given respiratory protection. When the inevitable lung damage takes place, the statistical record would reflect the need for respiratory protection, and it would be issued. Then, again, when the record shows later that there are no longer any respiratory problems, the respirators will be withdrawn in accordance the with CDC-type decision logic because they are clearly unnecessary. Such an approach is obviously not providing the necessary protection for the workers.

The CDC Risk Assessment logic, when applied to the selection and use of respirators, is flawed. OSHA states in 1910.134 that "respirators shall be selected on the basis of hazards to which the worker is exposed." This is very different from stating, as the CDC Guidelines state, that respirators shall be selected on the basis of the observed rate of sickness. This principle, advocated by CDC, is contrary to good industrial hygiene practice and also is contrary to OSHA policy. NO OSHA inspector will accept a respiratory protection program based upon the Risk Assessment logic contained in the CDC Guidelines.

(d) THE CDC GUIDELINES DO NOT SPECIFY WHAT TYPE OF RESPIRATOR IS TO BE USED IN "HIGH RISK", "INTERMEDIATE RISK", AND "LOW RISK" AREAS OR GROUPS.

The CDC Guidelines, for example, containes a paragraph H, "Cough-Inducing Procedures". There is a statement in that paragraph that HCWs should wear respiratory protection when present in rooms or enclosures where cough-inducing procedures are being performed on patients who have, or are at a high risk of having, infectious TB. The CDC Guidelines do not specify the type or grade of respirator to be used. This specific information must be included in the Guidelines.

The Table S4-1 in the CDC Guidelines only adds confusion by including information on respiratory protective devices which do not meet the criteria listed in the CDC Guidelines paragraph G, Respiratory Protection. For example, Table S4-1 contains data for disposable DM and DFM respirators whereas the Table should state that such respirators fail to satisfy the criteria of these Guidelines, and must not be used to protect HCWs against TB.

The CDC Guidelines do not contain a straightforward recommendation to guide the wearer in selecting the correct respirator.

This is in notable contrast to the NIOSH Recommendations issued on September 14, 1992. NIOSH, in accordance with good industrial hygiene practice and in accordance with OSHA policy, considered those locations and procedures where confirmed or potential TB transmitters are present and then categorized those locations and procedures according to their potential for aerosolization of droplet nuclei into "high", "medium", "indeterminate" and "no possibility of exposure".

For example, "any cough-inducing procedure" is considered as a "high" potential for aerosolization of droplet nuclei, while "AFB isolation rooms" are considered as "medium potential".

The NIOSH Recommendation then proceeds, logically and in accordance with good practice and OSHA policies, to list the minimal acceptable respiratory protection for each of the categories. The CDC Guidelines do not contain a similar table and make no attempt to provide this needed information.

The CDC Guidelines need to specify what type or grade of respirator is to be acceptable under what conditions so that the HCWs will be given the correct respirator. The basis of the recommendation must be the hazard to which the wearer is exposed, and not the historical record of contracted illness. The types recommended should include battery-powered respirators for certain situations.

(e) THE CDC GUIDELINES HAVE REDUCED THE LEVEL OF PROTECTION RECOMMENDED BY NIOSH BY ACCEPTING CERTAIN DISPOSABLE RESPIRATORS AS ACCEPTABLE, WHILE THE NIOSH RECOMMENDATIONS CLASSIFY THEM AS NOT ACCEPTABLE.

In their Recommended Guidelines of September 14, 1992, NIOSH presented a very substantial body of evidence to support their stated conclusion that the face-seal leakage for cup-shaped disposable masks can be considerably higher than 20%. At this time there are no NIOSH recommended qualitative or quantitative fit tests for these masks. Therefore, NIOSH states, "the efficacy and reliability of the face seals on cup-shaped disposable masks are undependable because there is no proven 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".

Yet, despite the evidence and conclusion of NIOSH, the CDC Guidelines include a set of criteria and associated data allows certain disposable respirators to be used. Table S4-1 in the CDC Guidelines, for example, includes an an entry claiming that the face-seal leakage of a Hepa disposable respirator cannot exceed 10%. The NIOSH body of data does not support this figure, but supports the conclusion that the face-seal leakage of any disposable respirator can be considerably greater than 20%.

Disposable, cup-shaped respirators should not be acceptable for use against TB. CDC has offered no data to challenge the facts presented by NIOSH.

(f) THE LEVEL OF RESPIRATORY PROTECTION INCLUDED IN THE CDC GUIDELINES IS SIGNIFICANTLY WORSE THAN THE LEVELS REQUIRED BY OSHA FOR PROTECTION AGAINST OTHER SERIOUS OCCUPATIONAL HAZARDS.

In their Recommended Guidelines, NIOSH recognizes TB transmission as a very serious occupational hazard and recommends, therefore, very effective respirators. The CDC Guidelines also recognizes TB transmission as a very serious occupational hazard, but do not recommend very effective respirators. Instead, the CDC Guidelines accept for protection against TB the kind of respirators that OSHA does not allow for use against serious hazards due to particulates or aerosols, and which NIOSH does not recommend, specifically, for protection against TB.

For example no disposable respirators are allowed in OSHA's lead standard (1910.1025), or OSHA's asbestos standard (1910.1001). This is because of a very substantial body of evidence and technical support demonstrating that disposable respirators are not capable, even with Hepa filtration capabilities, of providing reliable protection.

Despite the recommendation of NIOSH and the established policy of OSHA, CDC has set up criteria and offered unsubstantiated performance information to allow the use of disposable respirators.

These CDC Guidelines, if adopted, will deliberately provide much lower levels of respiratory protection for HCWs than the levels provided for other workers exposed to serious hazards. It appears that CDC believes that HCWs are in occupations which are different, so established industrial hygiene principles and precedents do not apply, and much lower levels of protection will suffice for the people at risk.

NIOSH must not permit the use of any type of disposable respirator for use against TB infection.

Kenneth V. Vaughan
President

Appendix 1

The Respiratory Protection Criteria listed

by CDC in the FR as part of the

"Draft Guidelines for Preventing the Transmission of TB in Health-Care Facilities, Second Edition : Notice of Comment Period", dated 12 October 1993

G. Respiratory Protection

• Respiratory protective devices used for M. tuberculosis should meet the following criteria:

1. The ability to filter particles 1 micron in size in the unloaded [1] state with a filter efficiency of ≥95% (i.e., filter leakage of ≤5%), given flow rates of up to 50 liters per minute.

Available evidence suggests that infectious droplet nuclei are in the 1–5 micron size range, therefore respirators used in health-care settings should be able to filter the smallest particles in this range efficiently. Fifty liters per minute is a reasonable estimate of the highest flow rate a HCW is likely to achieve during breathing even with strenuous work activities.

2. The ability to be qualitatively or quantitatively fit tested in a reliable way (47—ANS/1992) [2] to obtain a face-seal leakage of no more than 10% for most workers.

3. The ability to fit HCWs with different facial sizes and characteristics, which can usually be met by the availability of at least three sizes of respirators.

4. To ensure proper protection, the facepiece fit should be checked by the wearer each time he or she puts on the respirator, in accordance with OSHA's standard and good industrial hygiene practice.

• The OSHA respiratory protection standard requires that all respiratory protective devices be certified by NIOSH (48—20 CFR 1910.134). Respirators with HEPA filters are the only currently available certified respirators that meet or exceed the performance criteria stated above. Although DM and DFM filters are certified, these criteria are not evaluated. Current NIOSH certification procedures require that DM and DFM filters filter 99% of silica dust, but the certification process does not include adequate tests for filter efficacy against low-concentration aerosols in the size range of droplet nuclei. There is evidence that some respirators with DM and DFM filters do meet these criteria. However, at the present time, the certification process does not determine which NIOSH-certified DM and DFM filters meet these performance criteria.

• Appropriate respiratory protection should be worn by persons potentially exposed to M. tuberculosis in settings where administrative and engineering controls may not provide adequate protection (Supplement 4). Such settings include TB isolation rooms and rooms or enclosures in which patients who may have infectious TB are undergoing cough-inducing or aerosol-generating procedures. Other such settings may include transport of patients who may have infectious TB in emergency transport vehicles, or when urgent surgical or dental care must be provided to a patient who may have infectious TB before the patient can be treated with anti-TB medications and rendered noninfectious.

• In some settings, the risk of TB transmission may be estimated in the risk assessment or the best judgment of infection control staff to be so high that respiratory protection exceeding these criteria may be considered appropriate. In such settings, consideration may be given to the use of higher levels of protection (Table S4–1). Characteristics of a variety of currently available respiratory protection devices are summarized in Table S4–1.

• Health-care facilities in which respiratory protection is used for protection against inhalation of M. tuberculosis are required to develop, implement, and maintain a respiratory protection program (Supplement 4). All HCWs who need to use respiratory protection should be included in this program.

[1] Some filters become more efficient as they become loaded with dust. Health-care settings do not have enough dust in the air to "load" a filter on a respirator. Therefore, the filter efficiency for respirators used in health-care settings must be determined in the unloaded state.

[2] If quantitative fit testing is conducted, because of the well-documented deterioration of protection provided by respirators in the actual workplace compared to that obtained during a fit test, it is established industrial hygiene practice to require a fit test protection factor that is 10 times the assigned protection factor (APF) rating of the testing respirator. Thus, a quantitative fit test would require a fit factor of 100 to guarantee no more than 10% face-seal leakage for most workers in the workplace.

Appendix 2

NIOSH Recommended Guidelines
for Respiratory Protection of
Workers exposed to TB.

CDC

CENTERS FOR DISEASE CONTROL

NIOSH Recommended Guidelines

for

Personal Respiratory Protection

of Workers in Health-Care Facilities

Potentially Exposed to Tuberculosis

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health
Atlanta, Georgia

September 14, 1992

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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.

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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

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[redacted]

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 mainte-

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*.

II. Mode of Airborne Transmission and Potential for Worker Exposure

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. Hurton 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,

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.

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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).	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).	Up to 2% seal leakage under routine use conditions 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.	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.	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 masks is uncertain, since there are no proven fit tests for them and they cannot be fit checked.	Face-seal efficacy with these masks is uncertain, since there are no proven fit tests for them and they cannot be fit checked.	Face-seal efficacy with these respirators is predictable, since they can be both fit tested and 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.	These NIOSH-certified masks are not NIOSH tested for hazardous face-seal leakage during the certification process.	These NIOSH-certified respirators have been NIOSH tested for their face-seal efficacy 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).	Only one facepiece size is generally available that tends to produce higher leakages on small facial sizes (e.g., women, Hispanics, Asians).	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 facepieces, 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

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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).

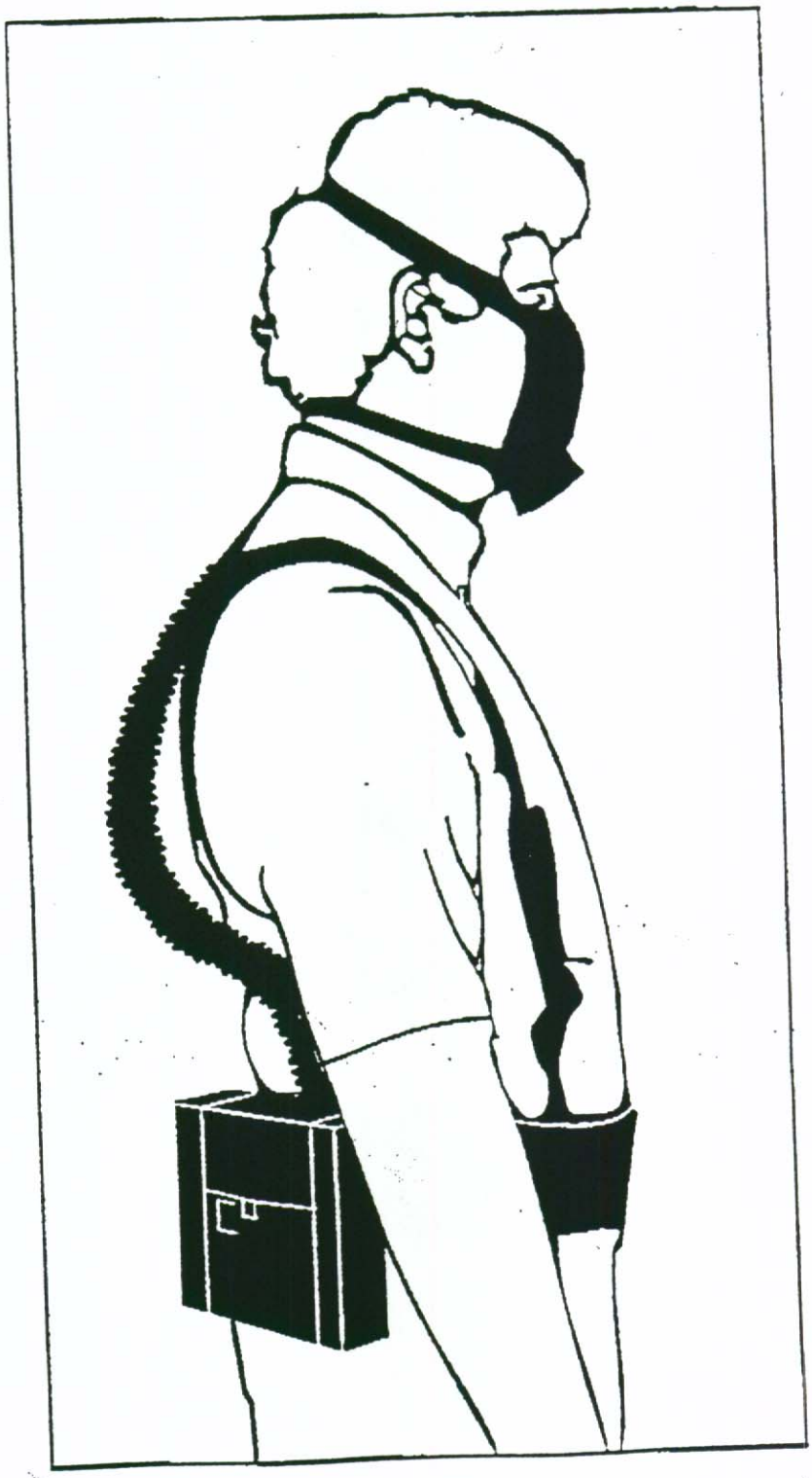


Figure 2—Example B of a NIOSH-Certified Powered, HEPA-Filter, Halfmask Respirator (MSA OptimAir™ 6A, NIOSH approval TC-21C-513).

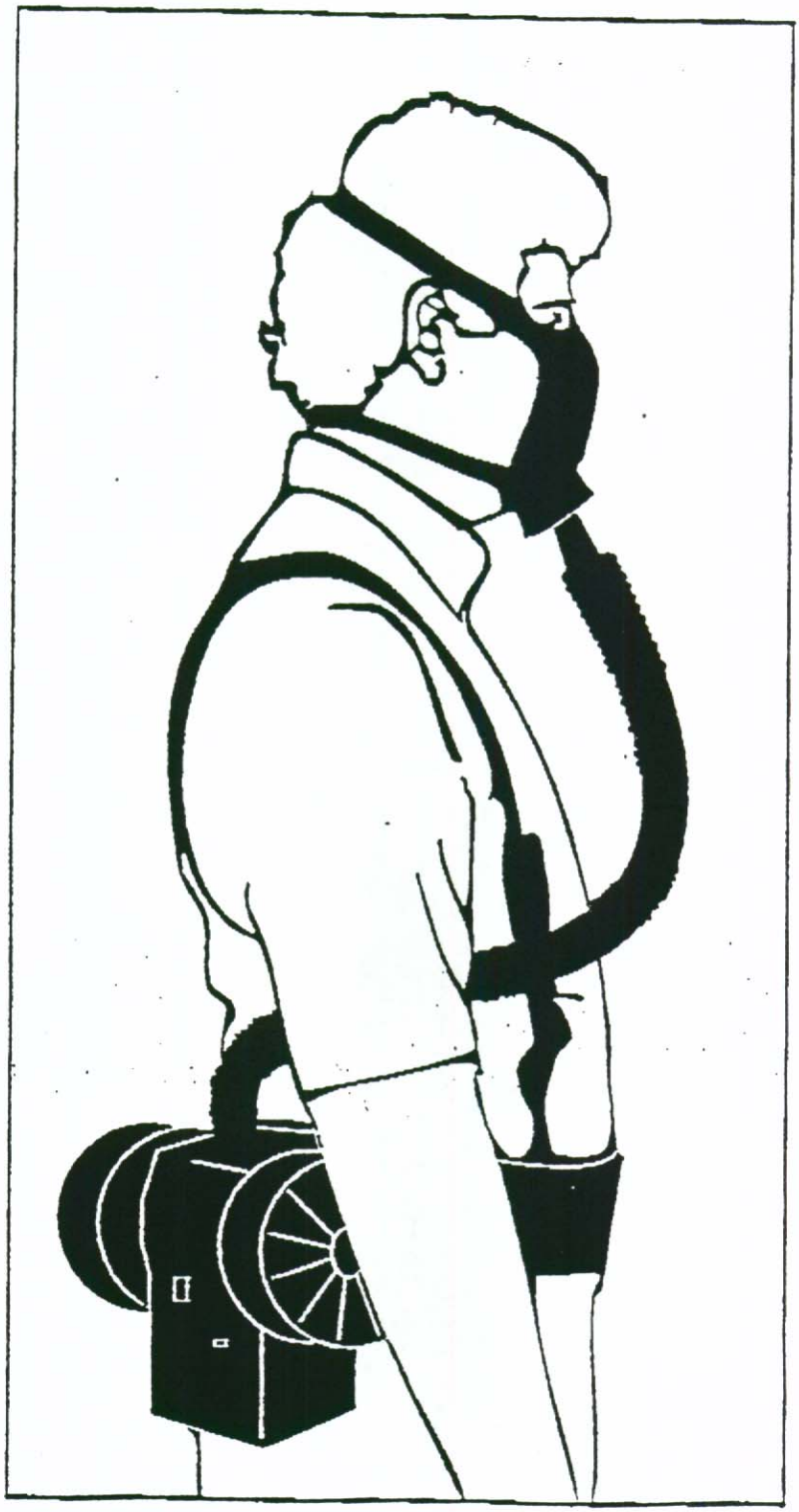
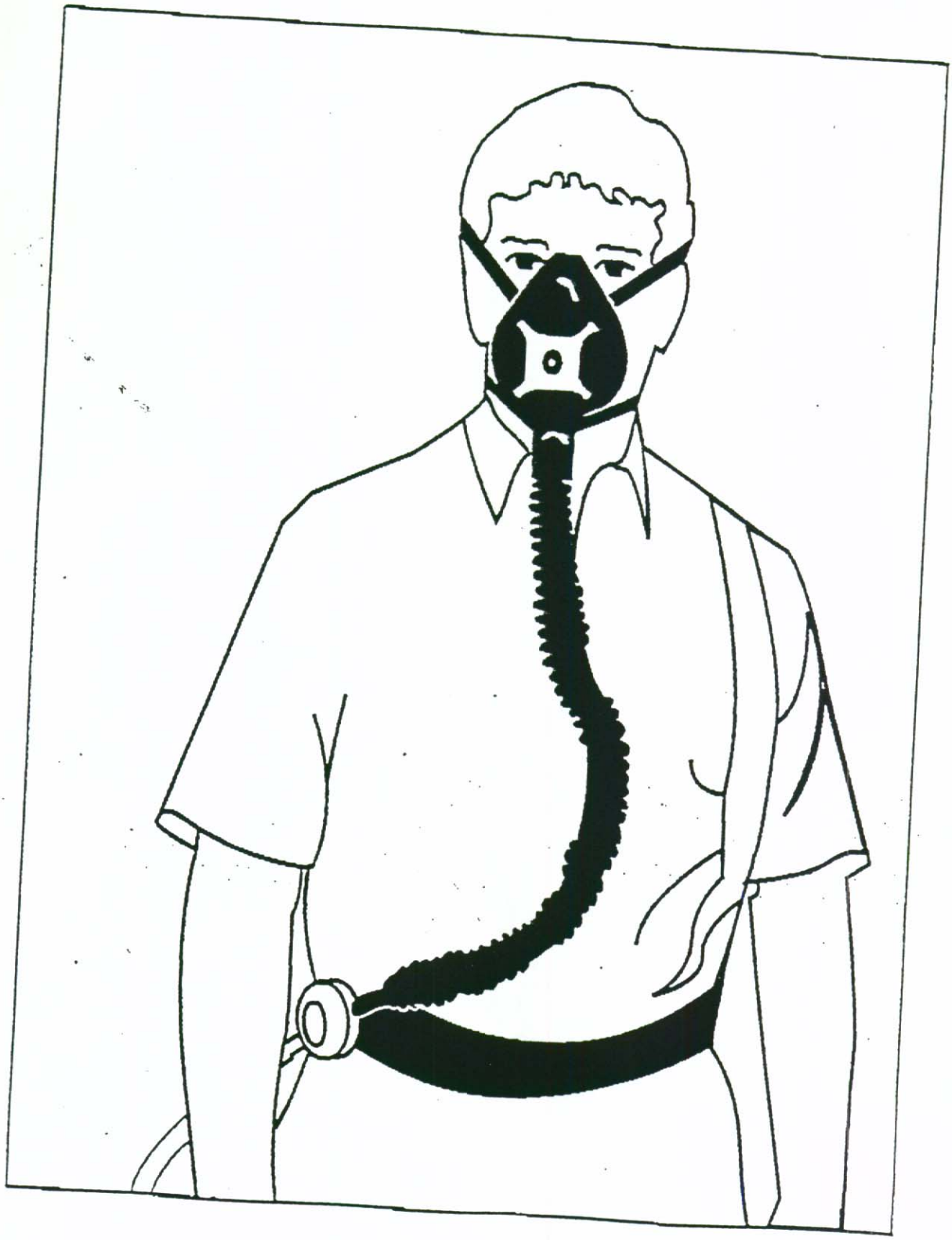


Figure 3—Example C of a NIOSH-Certified, Positive-Pressure, Air-Line, Halfmask Respirator (MSA Pressure Demand Air-Line Respirator, NIOSH approval TC-19C-158).



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.