

**North Carolina Department of Labor
Occupational Safety & Health Division
Raleigh, NC**

Chapter 7
Subchapter 7F

CFR Revision 146C

Field Information System
Respiratory Protection for M. tuberculosis
29 CFR 1910.139

Final Rule; Revocation

Discussion:

On August 25, 1993, the Coalition to Fight TB in the Workplace petitioned OSHA to promulgate both an Emergency Temporary Standard (ETS) under Section 6(c) of the OSH Act and a permanent occupational health standard under section 6(b) of the Act to protect workers from occupational exposure to tuberculosis (TB). This action was in response to a resurgence of TB in the early 1990's, as well as the emergence and prevalence of multi-drug resistant TB (MDR-TB) and the failure of most workplaces to effectively implement existing TB guidelines issued by the Centers for Disease Control and Prevention (CDC).

OSHA issued an enforcement directive on October 8, 1993 to address occupational exposure to TB. (This directive was updated on February 9, 1996.) This directive stated that although OSHA did not have a standard on occupational exposure to TB, some of the existing standards could be applied as well as the General Duty Clause. For example, the Respiratory Protection Standard, 29 CFR 1910.134, requires employers to provide protection to employees exposed to airborne hazards. When this standard was revised in 1998, the earlier version was recodified to 1910.139 as an interim standard governing the use of respirators used to protect against TB.

On December 31, 2003 (68 FR 75768), federal OSHA withdrew its proposed standard on occupational exposure to tuberculosis (TB) (62 FR 54160, October 17, 1997) in response to the steady decline and dramatic drop in the number of TB cases since OSHA began work on the proposed standard in 1993. This decrease in TB cases has been attributed to a broad range of Federal and community initiatives that were implemented. Hospitals, which are the occupational settings where workers are likely to have the highest risk of exposure to *Mycobacterium tuberculosis*, the bacteria that causes TB, have been noted to be in substantial compliance with Federal guidelines for preventing the transmission of TB.

In addition, OSHA stated that a standard is unlikely to result in a meaningful reduction of disease transmission caused by contact with the most significant remaining source of occupational risk, that is, exposure to individuals with undiagnosed and unsuspected TB. Outside of a hospital setting, workers often will not identify suspect TB cases quickly enough to implement isolation procedures and other precautions before further exposure occurs.

Since OSHA terminated rulemaking on a standard for occupational exposure to TB, it has also revoked its interim TB respiratory protection standard (68 FR 75776) on December 31, 2003 and will begin applying the 1998 revised respiratory protection standard, 29 CFR 1910.134, for respirators worn to protect against exposure to TB. Because this standard contains more protective provisions and is more stringent in its requirements, for example, to implement a comprehensive written program, oversight by a qualified respiratory protection program administrator, annual fit-testing, annual training, and medical questionnaire, the revised 1910.134 is a more effective standard than its recodified predecessor, 1910.139.

Action:

In accordance with North Carolina General Statute 150B-21.5(c), the N.C. Commissioner of Labor adopted the federal revoking of 29 CFR 1910.139, Respiratory Protection for Tuberculosis with an effective date of June 30, 2004. Reference the *Federal Register* (Volume 68, No. 250) for the details related to this action.

(Signed on Original)

Allen M. McNeely
Director

3/02/2004

Date of Signature

N.C. Effective Date: June 30, 2004

NCAC Number: 13 NCAC 7F.0101

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1910**

[Docket No. H-371]

RIN 1218-AA05

Respiratory Protection for M. Tuberculosis**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.**ACTION:** Final rule; revocation.

SUMMARY: OSHA is revoking “Respiratory Protection for M. Tuberculosis” (29 CFR 1910.139) which is simply a recodification of OSHA’s 1971 General Industry Respiratory Protection standard that was revised in 1998. At the time of the revision of the 1971 standard, OSHA decided that, because its proposed standard for occupational exposure to TB, published three months earlier, included a comprehensive respiratory protection provision, the Agency would allow compliance with the previous respirator standard for TB protection until completion of the TB rulemaking. Thus, pending conclusion of the TB rulemaking, OSHA redesignated the old Respiratory Protection Standard in a new section entitled “Respiratory Protection for M. tuberculosis”. However, in a document published elsewhere in this separate part of the **Federal Register**, OSHA is today withdrawing its proposed TB standard. Because this withdrawal concludes the TB rulemaking, OSHA is revoking the redesigned Respiratory Protection Standard, and will begin applying the General Industry Respiratory Protection Standard (29 CFR 1910.134) to respiratory protection against TB.

DATES: This revocation is effective December 31, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

On October 17, 1997, OSHA published its Notice of Proposed Rulemaking (NPRM) for Occupational Exposure to TB (62 FR 54160). In the proposal, the Agency made a preliminary determination that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings were at

significant risk of incurring TB infection while caring for their patients and clients or performing certain procedures. The Agency also preliminarily concluded that this significant risk can be minimized or eliminated using infection prevention and control measures that have been demonstrated to be highly effective in reducing or eliminating job-related TB infections. These measures included the use of respiratory protection when performing certain high-hazard procedures on infectious individuals.

On January 8, 1998 OSHA revised its 1971 General Industry Standard for Respiratory Protection (63 FR 1152). Because the 1997 TB proposal included all of the respiratory protection provisions that OSHA believed would be applicable to respirator use for TB protection, the Agency did not require this use to comply with the new § 1910.134 during the rulemaking proceedings on the TB proposal. Instead, pending conclusion of the TB rulemaking, OSHA redesignated the old § 1910.134 as § 1910.139, “Respiratory protection for M. tuberculosis.”

However, OSHA is today withdrawing its proposed TB standard (*see* Occupational Exposure to Tuberculosis; Proposed Rule; Withdrawal published elsewhere in this **Federal Register**), and with this document is revoking 29 CFR 1910.139.

II. Reasons for the Revocation of 29 CFR 1910.139

OSHA is revoking 29 CFR 1910.139 because it was intended to apply only during the pendency of the TB rulemaking, and that rulemaking is being terminated. The standard being revoked is simply a recodification of OSHA’s 1971 General Industry Respiratory Protection Standard, 29 CFR 1910.134, which was revised in 1998. (63 FR 1152, (January 8, 1998)). At the time of the revision, OSHA decided that, because the TB proposal issued three months earlier included a self-contained respiratory protection provision, the Agency would allow compliance with the previous respirator standard for TB protection until completion of the TB rulemaking. (62 FR 54289); (63 FR 1180). To accomplish this, OSHA redesignated the old § 1910.134 as § 1910.139, “Respiratory protection for M. tuberculosis.” OSHA made clear in both rulemakings, however, that it intended the respiratory protection requirements ultimately made applicable to TB protection to be consistent with the revised § 1910.134, and the TB proposal was itself consistent with that revision. (62 FR 54257, 54287-54288; 63 FR 1180). In

fact, the relevant comments from the Respiratory Protection rulemaking were made part of the TB rulemaking. (Exs. 150-1 through 150-178). With this termination of the TB rulemaking, it is now appropriate for OSHA to begin applying the revised 29 CFR 1910.134 to respiratory protection against TB.

Applying the General Industry Respiratory Protection standard to the use of respirators for TB protection is supported by the records in both the TB and respirator rulemaking proceedings. OSHA noted in the proposed TB rule that one option was to apply the general respirator standard to TB protection. (62 FR 54257). A number of participants in the TB rulemaking urged OSHA to take this course. (*See, e.g.*, Exs. 17-215; 17-271; 17-455; 17-570; 17-906; 17-1145). The proposed TB standard’s respiratory protection requirements were largely consistent with those in the revised general industry standard. One of the hazards the latter standard was designed to address is the “inhalation of bacteria * * * including tuberculosis.” (63 FR 1159).

The revised general industry standard reflects the Agency’s evaluation of current knowledge and technology as they relate to effective respiratory protection programs. The revisions help to ensure that employers have sufficient guidance to select and maintain appropriate respiratory protection. Given the extensive rulemaking undertaken to establish these requirements, and the intensive review and consideration of all issues related to respiratory protection in that rulemaking, the Agency believes it is appropriate and necessary to ensure that employees exposed to TB have the same protections as employees exposed to other types of hazards in the workplace. All facilities that use respirators for any purpose other than TB protection are already required to comply with the revised respiratory protection standard. The revised standard has also been upheld in its entirety by the U.S. Court of Appeals for the Eleventh Circuit. *AISI v. OSHA*, 182 F.3d 1261, 1273 (11th Cir. 1999).

The new requirements in the revised respiratory protection standard include updating the facility’s respirator program, complying with amended medical evaluation requirements, annual fit testing of respirators, and some training and recordkeeping provisions. These provisions were also included in the TB proposal, and the only one that elicited significant comment was the requirement for annual fit testing.

With regard to updating each facility’s respiratory protection program,

§ 1910.139 provides the skeletal requirements for such a program, but does not elaborate on what would be required in each element. The revised respiratory protection rule provides employers with additional guidance on what constitutes an appropriate and effective program, giving employers a better road map to follow when relying on respiratory protection in the workplace. It is the Agency's view, supported by the Respiratory Protection rulemaking record, that an effective program requires a systematic approach to evaluating workplace conditions, selecting the appropriate respirator, ensuring the respirator fits, and maintaining the respirator properly. The revised standard specifies how this systematic approach is to be implemented in the workplace.

Similarly, § 1910.139 requires medical evaluation, but does not set forth the components of the evaluation, or how it is to be accomplished. The medical evaluation provisions of the revised § 1910.134 set forth the minimum requirements employers must implement to determine if employees are medically qualified to wear respirators in their places of work. The employer must provide a medical evaluation for each covered employee, performed by either a physician or another licensed health care professional. Information from the medical evaluation is to be used to determine the employee's eligibility to wear the respirator proposed for the employee. The employer must base the determination on the recommendation of the health care professional. Administration of the medical questionnaire in § 1910.134, Appendix C, is a further requirement.

The medical evaluation provisions of revised § 1910.134 are significantly better than the original standard. They ensure that the health care professional, the employee, and the employer are aware of the factors that must be considered in evaluating an employee's respiratory protection needs, and provide the tools to ensure appropriate decisions are made.

With regard to employee training, § 1910.139 states only that employees must be "instructed and trained in the proper use of respirators and their limitations," with no provision for annual retraining. Revised § 1910.134 requires employers to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable and recur at least annually. Employers must provide the training before their employees are required to use the respirator. Topics to be covered include

why the respirator is necessary, what the limitations of the equipment are, how to use the respirator in emergencies, how to use and care for the equipment, and how to recognize the medical signs and symptoms that may limit or prevent the use of respirators. OSHA has determined that these more detailed requirements regarding employee training will help to ensure that the training provided is appropriate and effective, thus leading to a more effective workplace respiratory protection program.

Section 1910.134 requires more recordkeeping than § 1910.139. Section 1910.134 consolidates recordkeeping requirements with respect to medical evaluations, fit testing and the respirator program into one section of the standard. Commenters agreed that such consolidation of requirements would improve understanding of the standard's recordkeeping obligations (Exs. 54–267; 54–286).

Both § 1910.139 and § 1910.134 recognize that fit testing is an important component of an effective respiratory protection program. Fit testing is necessary because a respirator that does not fit properly provides only the illusion of protection. While it has long been known that fit can affect respiratory protection significantly, particularly for these types of respirators that depend on filtering the contaminant (rather than providing a separate source of uncontaminated air), specific protocols for fit testing are a more recent development. The revised § 1910.134 reflects this newer technology, and provides specific guidance on appropriate fit testing procedures. OSHA believes that following these types of procedures is necessary to ensure that respirators are really providing the protection needed.

The frequency of fit testing was an issue in both the Respiratory Protection and TB rulemakings, and it generated significant comment in both records. There was little dispute that some additional fit testing beyond the initial test is necessary because respirator fit can be affected by a number of factors, including the size and shape of a person's face, dental changes, changes in the types of movements required to perform work when wearing the respirator, and the presence of facial hair. As OSHA explained when it promulgated the annual retesting requirement in 29 CFR 1910.134, waiting more than a year between fit tests allows a substantial fraction of workers to lose the protection respirators provide (63 FR 1224). This is no less true when respirators are used for TB protection than it is when they

are used for protection against other hazards.

Consistent with current practice, CDC guidelines and NIOSH recommendations, and the selection criteria in § 1910.134, OSHA anticipates that half-mask N95 air-purifying filtering facepiece respirators will be the primary type of respirator used for TB protection. This type of respirator has a securely-fitting facepiece that filters the air, preventing inhalation of contaminants. Effective protection requires a good face-to-facepiece seal in order to ensure that there are no gaps through which contaminated air can enter the facepiece and be breathed in by the worker. Thus in order to provide protection, the respirator must fit the employee well enough to prevent leakage from occurring. This is particularly important for a hazard such as TB that does not have any warning properties that would allow an employee to detect that it is being inhaled, *e.g.*, there is no odor that might indicate a breakthrough.

The proposed TB standard acknowledged these issues by proposing that fit testing be performed as follows. Each employee who would have been required to wear a tight-fitting respirator would have had to pass a fit test at the time of initial fitting of the respirator; whenever changes occurred in the employee's facial characteristics that affected the fit of the respirator; and whenever a different size or make of respirator was assigned for use by that employee. At a minimum, the proposal would have required fit tests to be conducted annually unless an annual medical evaluation (also required by the proposal) indicated that a fit test was not necessary. The revised respiratory protection standard imposes the same requirements, except that it does not require annual medical evaluations, and annual fit tests are required for all respirator users.

Several commenters supported the proposed provision allowing a licensed health care professional to determine the need for an annual fit test during a face-to-face evaluation. (*See, e.g.*, Exs. 17–671; 17–454; 17–932.) However, others argued compellingly that there are no objective data demonstrating that it is possible to determine whether a respirator fits by examining a person's face. (*See, e.g.*, Exs. 17–271; 17–697; 18–60A; 17–455; 17–768; 17–920).

A number of commenters argued that repeat fit testing should only be done when the respirator changes, or when there is a significant change in the employee's physical condition that may interfere with the facepiece seal (*see, e.g.*, Exs. 150–56; 150–69; 150–125).

Some infection control professionals cited additional costs and a perceived lack of benefits from repeating fit testing on an annual basis. (See, e.g., Exs. 17-671-I; 17-671-X; 17-211; 17-464; 189-22; 183-15; 183-13.) In particular, the Infectious Disease Society of America cited studies by Blumberg *et al.* that examined tuberculin skin test conversion rates before and after the implementation of expanded TB control measures at a large metropolitan hospital. (Exs. 189, p. 22; 18-5300; 7-173.) The implementation of expanded controls, which included retrofitting rooms into negative-pressure isolation rooms, expanding respiratory isolation policies, 6-month skin testing of all health care workers, and the addition of NIOSH certified respiratory protection, led to a 90% reduction in skin test conversions. Because annual fit testing was not a part of the expanded infection control program, the IDSA asserted that these studies demonstrate that there is no benefit to annual fit testing.

The fact that a single study of workers whose respirators were fit tested only once did not show excess TB infections does not overcome the evidence supporting OSHA's conclusion in the revised respiratory protection standard that "annual fit testing * * * is appropriate to protect employee health" (63 FR 1224). The studies by Blumberg, *et al.* were not designed to study the efficacy of fit testing but rather the efficacy of an overall expanded TB infection control program in which many different protective measures were implemented simultaneously. Thus, it is difficult, if not impossible, to determine the relative efficacy of any one measure. Moreover, not all exposed workers would have been infected even without respirators. In the absence of periodic fit testing, there is no way to determine which of the exposed workers were wearing properly fitting respirators. It is the fit of a respirator that determines its effectiveness, and the record contains no evidence indicating that factors affecting fit are different for TB-exposed workers than they are for other workers.

A large number of participants in both the respiratory protection and TB rulemakings supported annual fit testing (see, e.g., Exs. 150-23; 150-24; 150-27; 150-45; 150-52; 150-53; 150-58; 150-74; 150-89; 150-93; 150-96; 150-103; 150-117; 150-123; 150-45; 150-52; 150-141; Respiratory Protection Hearing TR, pp. 1573, 1610, 1653, 1674). These participants agreed that fit is not static, and that a one-time, initial fit test without a requirement for annual re-fitting does not ensure that the appropriate level of protection would

continue to be provided over time. A number of participants in the TB rulemaking suggested that the respiratory protection standard be applied in its entirety for protection from TB exposures. For example, Health Evaluation Programs, Inc. indicated:

Respirator fit testing is not a hazard-specific or industry specific activity. It is specific to tight-fitting respirators worn by people. OSHA recognized this when the new Respiratory Standard 29 CFR 1910.134 was released on January 8, 1998. The fit testing provisions of this new standard replace those found in the various substance-specific OSHA standards. Likewise, there is no reason to make an exception for TB. The respirator either provides the level of fit it is rated for, or it does not. (Ex. 17-570)

This commenter went on to state:

OSHA's responsibility to base a final standard on the best respirator information available can best be served by incorporating what OSHA has already learned and decided regarding respirator fit testing frequency.

Another commenter, Certified Industrial Hygienist David L. Spelce, noted the particular aspects of TB exposures that indicate fit testing is necessary to ensure proper fit for protective purposes, as well as reinforcing the training aspects of fit testing that help employees don respirators appropriately:

Annual fit testing provides the opportunity for employees to receive feedback on how well they are donning their respirator. TB droplet nuclei have no warning properties such as taste, odor, or irritation. Employees cannot detect if TB droplet nuclei leak into their respirators. Qualitative fit test challenge agents are detectable by odor, taste, or irritation and provide instant feedback as to how well the respirator fits and if the respirator was properly donned. Quantitative fit tests also provide instant feedback to employees through instrumentation. Employees need fit testing annually as part of training to ensure they don the respirators correctly so that the respirator properly seals to their face. Fit testing is one of the respirator program elements that is essential to ensure the respirators issued to employees provide the protection factor assigned to that particular class of respirator. (Ex. 17-920)

(See also Exs. 17-455; 17-591; 17-717; 18-53; 183-7).

Some commenters who supported the concept of periodic fit testing suggested varying time intervals for that testing, either more or less frequent than annually. (Exs. 150-16; 150-55; 150-124; 54-290.) NIOSH, in addition to its support for applying all of the provisions of the revised § 1910.134 to TB exposures, also supported periodic fit testing for those exposures. (Exs. 18-60A; 189-36.) NIOSH suggested that, in the absence of TB-specific data on the appropriate fit testing interval, the

"record for and the provisions of 29 CFR 1910.134 [would] be the best guide." (Ex. 18-60A.)

It should also be noted that the annual fit testing requirement of the revised respiratory protection standard was specifically challenged in court, and was upheld. The court concluded that the requirement is supported by substantial evidence in the record, even though "some evidence" indicated that such frequent retesting might not be necessary. 182 F.3d at 1273.

In summary, OSHA believes that the provisions of revised § 1910.134 represent the Agency's assessment of the best information available at the time that rule was issued to ensure that respiratory protection in the workplace is effective. In order to extend similar protection to workers exposed to TB in the workplace, OSHA will apply all of the provisions of § 1910.134, including annual fit testing to TB exposures. Because of the current widespread adherence to § 1910.134, and the ongoing nationwide decline in active TB, the Agency believes the rulemaking records for both the revised respiratory protection standard and the proposed TB standard support such an approach to respiratory protection.

III. Summary of the Final Economic Analysis and Regulatory Flexibility Certification

Introduction

By including TB-related respirator use in Section 134, OSHA is imposing some new requirements on employers who require their employees to use respirators for this purpose. However, this action is not a significant rulemaking under Executive Order 12866, or a "major rule" under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501) or Section 801 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 601). Even though this action does not meet any of the criteria for an economically significant or major rule specified by the Executive Order or relevant statutes, as shown in the remainder of this summary of the Final Economic Analysis and Regulatory Flexibility Certification, it was reviewed by OMB pursuant to E.O. 12866. (The full analysis this summary relies upon has been entered into the docket as Ex. 192.)

Affected Establishments

The scope of this action is limited to establishments in the health services industry (SIC 80) that follow the CDC guidelines and provide respiratory protection for employees potentially exposed to tuberculosis. These

establishments are primarily hospitals. To the extent that patients with active tuberculosis may be treated in other health services facilities, such as those that may be affiliated with nursing homes, correctional facilities, or substance abuse treatment facilities, these may also be potentially affected by this action.

An estimated 6,500 establishments are potentially affected by this action. The employees who would be covered are those using respirators for protection against occupational exposure to TB. Unfortunately, there are no data showing exactly how many persons use respirators for the purpose of protecting against occupational exposure to tuberculosis. For the purposes of this analysis, OSHA is using a BLS estimate of the number of persons using filtering face piece respirators in the health care sector. This results in an estimate of 638,000 affected employees. Using this estimate overestimates the number of respirator users using respirators for occupational exposure to TB by including respirator users in unaffected sectors and by including employees using respirators for reasons other than occupational exposure to TB. However, the estimate may exclude some employees who should be using respirators for occupational exposure to TB and are not doing so.

An estimated 5,312 of the potentially affected establishments are small entities. Small entities were identified in accordance with the definitions established by the Small Business Administration, as specified in the Regulatory Flexibility Act. These small entities employ approximately 457,000 of the employees potentially affected by this action.

Benefits

The employees covered by this action are those using respirators for protection against potential occupational exposure to tuberculosis. The reduction in risk achieved through compliance with the requirements of this action will result in reductions in the numbers of infections, active disease cases, and fatalities occurring among the covered workers. Although the employees working in establishments covered by this action will be the primary beneficiaries of the increased protection provided by the standard, many other individuals will also benefit from the standard because tuberculosis is a communicable disease.

For the final respirator program standard, OSHA concluded based on the best available evidence that from 5 to 50 percent of employees would lack a proper fit without annual fit testing. OSHA further concluded that overall,

moving from full compliance with the old standard to full compliance with the new standard would reduce exposures by 27 percent on average across all employees covered by the respirator protection program. OSHA estimates that this action will have similar effects in reducing the number of infections, active disease cases, and fatalities occurring among the covered workers.

Technological Feasibility

In accordance with the provisions of the OSH Act, OSHA has reviewed the requirements of this action and has assessed their technological feasibility. As a result of this review, OSHA has determined that fulfilling the resulting requirements of this action is technologically feasible.

Compliance with the requirements of the action can be achieved with methods and measures that have already been developed and implemented in many establishments already under the respirator protection standard. As established in the final respiratory protection standard, the standard's provisions in the respirator program standard require only technology that is currently and readily available and widely in use. There is no barrier to applying these technologies in a health care setting. In fact, the requirements added by this action are already applicable to and have already been implemented in many of the affected health care establishments to the extent that any use of respirator protection is occurring for purposes other than protection from occupational exposure to tuberculosis.

Costs of Compliance

When OSHA promulgated its final respiratory protection standard in 1998, all potentially affected establishments and employees, including those in the health services industry and those using respirators only for protection from tuberculosis, were included in the analysis of the costs of compliance and potential impacts. This was done because of uncertainty as to the extent to which respirators were being used for protection against occupational exposure to tuberculosis. Thus, the conclusions and determinations regarding impacts and feasibility associated with the provisions of the standard for these establishments have already been established by the evidence in the record and other documents and decisions associated with the rulemaking. Nevertheless, the final economic analysis for this action analyzes the full economic impacts of this action alone. Using the estimate of the number of respirator users provided

by BLS, which probably overestimates the number of affected employees, the total annualized estimated costs for this action are \$11.7 million, as shown in Table 1. The largest component of the costs is comprised of the requirements associated with employee fit-testing and training (which OSHA assumes will be done at the same time), which account for about 92 percent of the total costs, or \$10.7 million. Costs associated with revising respirator programs and with the recordkeeping requirements have an estimated annualized cost of about \$1 million. Given these costs, this action is not an economically significant rule with respect to EO 12866.

TABLE 1.—COMPLIANCE COSTS ASSOCIATED WITH REVISED REQUIREMENTS FOR RESPIRATORY PROTECTION

Type of cost	Annualized incremental costs
Respirator Program	\$325,000
Fit Testing And Training	10,716,719
Recordkeeping	638,000
Total	11,679,719

Economic Feasibility

In order to assess the nature and magnitude of economic impacts, OSHA compares the estimated costs of compliance to industry revenues and profits. The estimated compliance costs represent less than 0.005 percent of the revenues of the affected establishments in the hospital sector. The estimated compliance costs also represent about 0.08 percent of profits among affected for-profit establishments. For these establishments, the costs of compliance with the OSHA action would also be economically feasible. The affected establishments face more significant increases in costs or reductions in revenues on a continuing basis, through changes in rent, labor costs, utility costs, and costs of other resources purchased, through changes in levels of donations and contributions provided, and through changes in government funding levels. Even if such costs cannot be passed on to consumers, changes in revenues or profits of this magnitude will not threaten the existence or competitive structure of an industry [the test for economic feasibility stated in *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1272 (D.C. Circuit 1980)].

Regulatory Flexibility Screening Analysis

OSHA also analyzed the potential economic impacts of this action on

small entities (as defined in accordance with SBA criteria) and on very small establishments (those with fewer than 20 employees). For small entities as defined by SBA criteria, the costs represent 0.008 percent of revenues and 0.21 percent of profits (for those entities which are not nonprofits). For small entities with fewer than 20 employees, the cost also represents 0.008 percent of revenues and 0.21 percent of profits (for those entities which are not nonprofits). OSHA's Procedures define a significant impact as one in which the costs exceed 1 percent of revenues or 5 percent of profits. OSHA therefore certifies that this final regulation will not have a significant impact on a substantial number of small entities.

Unfunded Mandates Analysis

OSHA reviewed this action according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed above in the Final Economic Analysis and Regulatory Flexibility Certification of this preamble, the Agency has determined that this action imposes less than \$100 million in costs in any given year on either private or public sector entities. As a result, this is not a major rule under UMRA. OSHA standards do not apply to state and local governments, except in states that have voluntarily elected to adopt a State Plan

approved by the Agency. Consequently, this action does not meet the definition of a "Federal intergovernmental mandate" (see section 421(5) of the UMRA (2 U.S.C. 658(5))). In conclusion, this action does not mandate that state, local, and tribal governments adopt new, unfunded regulatory obligations.

Paperwork Review

The paperwork burdens for this action were included in the final standard on Respiratory Protection, published January 8, 1998 (63 FR 1152). The OMB control number is 1218-0019.

Environmental Impacts

The provisions of this action have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 432, *et seq.*], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR part 1500], and OSHA's DOL NEPA Procedures [29 CFR part 11]. As a result of this review, OSHA has determined that this action will have no significant adverse effect on air, water, or soil quality, plant or animal life, use of land, or other aspects of the environment.

Authority and Signature

This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for

Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC, 20210. It is issued pursuant to sections 4, 6, and 8 of the Occupational and Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary's Order 3-2000, and 29 CFR part 1911.

Signed at Washington, DC, this 19th day of December, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

- For the reasons set forth in the preamble, 29 CFR part 1910, Subpart I is amended as follows:

PART 1910—[AMENDED]

- 1. The authority citation for Subpart I of part 1910 is revised to read as follows:

Authority: Sections 4, 6 and 8, Occupational Safety Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), or 5-2002 (67 FR 65008), as applicable. Sections 1910.132, 1910.134, and 1910.138 also issued under 29 CFR part 1911. Sections 1910.133, 1910.135, and 1910.136 also issued under 20 CFR part 1911 and 5 U.S.C. 553.

§ 1910.139 [Removed]

- 2. Section 1910.139 is removed.

[FR Doc. 03-31846 Filed 12-30-03; 8:45 am]

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