

January 21, 2004

John L. Henshaw  
Assistant Secretary of Labor  
Occupational Safety and Health Administration  
200 Constitution Avenue, NW  
Washington, DC 20210

Dear Assistant Secretary Henshaw:

On behalf of the Association for Professionals in Infection Control and Epidemiology (APIC), we are writing in response to OSHA's recent decisions to withdraw the proposed tuberculosis (TB) rule and at the same time to impose new requirements by enforcing the General Industry Respiratory Protection Standard for occupational exposure to *M. tuberculosis*.

First and foremost, we commend OSHA on the decision to withdraw the proposed TB rule. This decision was clearly based on clinical, epidemiologic and infection control principles, practices and evidence of TB control in health care and community settings. On the other hand, the rationale for imposing the additional mandates required by enforcing the General Industry Respiratory Protection Standard to occupational exposure to TB or to patients with any other potential infection has not been justified. Our concerns can be summarized as follows and will be elaborated upon in the text of this letter:

1. The General Industry Respiratory Protection Standard is not applicable to occupational exposure to patients;
2. Transmission of tuberculosis in health care facilities was controlled prior to the use of certified respirators and/or performing initial or annual fit-testing;
3. Current methods of fit-testing N-95 respirators are not reproducible, reliable or reflective of in-use situations; and
4. The decision to impose this new mandate was issued on December 31, 2003 (New Years Eve) without the opportunity to review or provide public comment.

**1. The General Industry Respiratory Protection Standard is not applicable to occupational exposure to patients.**

The General Industry Respiratory Protection Standard (1910.134) was developed to prevent adverse health effects caused by exposure to airborne chemical hazards (see pertinent legal

authority for the standard). Exposure to patients with potential TB infection is not the same as exposure to chemical toxins or particulates such as asbestos. Health care facilities are not like marine terminals, long shoring and construction sites that can pre-assess the potential for exposure and determine levels of contaminants. (See below)

1910.134 Respiratory protection. This section applies to General Industry (part 1910), Shipyards (part 1915), Marine Terminals (part 1917), Longshoring (part 1918), and Construction (part 1926). (a) Permissible practice. (1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

Health care facilities cannot measure or accurately determine the potential for exposure and/or the relevance when dealing with patients who may or may not have an infection; who may or may not have an infectious load capable of being transmitted; who may or may not have a way to disseminate their organisms; and who may or may not have an organism that is capable of being transmitted via airborne spread, etc.

Respiratory protection in health care serves two purposes: one, a physical barrier to block mucosal surfaces and the second, to filter particles of certain sizes. The ability to filter infectious particles is not the same as gases, fumes, etc. The particle size emanating from a patient and containing a pathogen is not the same size as the organism itself. It also is not the same size as that used to test respirators. In addition, respirator filter material is challenged with 0.3-micron size particles. Tubercle bacilli are slightly bent or curved slender rods approximately 2-4 microns in length and .2-.5 microns wide, but patients do not aerosolize pure free-floating microorganisms; their secretions and excretions are comprised of proteinacious or moisture-laden particles.

## **2. Transmission of tuberculosis in health care facilities was controlled prior to the use of certified respirators and/or performing initial or annual fit-testing.**

The resurgence of TB seen in the late 1980s and early 1990s has been attributed to numerous demographic, epidemiologic and clinical factors. Control of outbreaks and reduction in the number of reported cases have been clearly demonstrated. In the community, the major control strategies have involved prompt identification of cases, ensuring the initiation and completion of appropriate antituberculous therapy, identifying contacts and providing appropriate treatment to reduce the likelihood of clinical disease. In health care facilities, outbreaks of tuberculosis were controlled and prevented by early identification of cases, prompt isolation and appropriate

treatment. These outbreaks were controlled prior to the use of particulate respirators and fit-testing, when masks were the standard for protecting health care personnel.

In the *Federal Register* notice OSHA states, “OSHA has decided not to promulgate a standard addressing occupational exposure to TB because it does not believe a standard would substantially reduce the occupational risk of TB infection. ...Risk to workers encountering undiagnosed cases will be reduced most effectively by reducing even further the incidence of TB in the population as a whole, and therefore in their client populations.” Furthermore, OSHA states, “The occupational risk of TB infection is lower than that reflected in OSHA’s proposed standard. ....there is no dispute that occupational risk has declined as the incidence of TB in the population as a whole has declined.”

In the same notice, OSHA discusses the effectiveness of the TB control strategies that led to the containment of TB during the most recent resurgence (late 1980s, early 1990s); specifically, the issuance and implementation of CDC guidelines on this subject, and the efforts of the health care and public health communities. In particular, OSHA mentions the effectiveness of the CDC guidelines for preventing the transmission of TB in health care settings.

The CDC guidelines, as currently written, include the recommended use of respiratory protection for health care workers performing high-hazard procedures or working in TB isolation rooms. So on one hand, OSHA is praising the effectiveness of the CDC guidelines and on the other hand, OSHA is mandating an additional annual fit-testing requirement (within the general industry standard).

### **3. Current methods of fit-testing N-95 respirators are not reproducible, reliable or reflective of in-use situations.**

Prior to 1995, respirator certification procedures included a fit-testing component. This is no longer the case and should be reinstated. Rather than placing the responsibility on every employer and user, the regulatory process for manufacturers should include a fit-test component; only respirators with good facial fit characteristics should be certified and information regarding facial fit characteristics should be made available to employers and users. Priority should be given to the development and assurance of enhanced fit characteristics for particulate respirators for all uses under the General Industry Respiratory Protection Standard regardless of the applicability of this general standard to health care exposures to patients.

Various methods of fit-testing have been described, yet the validity, reliability, reproducibility and effectiveness of fit-testing and fit-testing methods have not been established. Indeed numerous studies have been published that would suggest that different methods produce different results, and the provision of fit-testing does not necessarily correlate with proper donning of respiratory protection in the work setting. In addition, the incremental benefit of fit-testing is dependent upon the fit characteristics of the device itself (i.e., if the respirator has inherently good fit characteristics, the incremental benefit is minimal).

As you are aware, in early 2000, Congress commissioned a third-party study of the proposed TB rule by the Institute of Medicine (IOM). Throughout the December 31, 2003 withdrawal notice, OSHA refers to important findings in the IOM study that reinforce the agency's decision to withdraw the proposed TB rule. It is interesting to note, however, that OSHA chooses not to cite the IOM's concerns on the subject of annual fit-testing of respirators, choosing instead to impose this requirement through an already-existing regulatory mechanism, for no apparent or justified reason. Had OSHA considered the IOM's conclusions on this subject, we are sure that the agency would again have found the CDC's recommendations completely adequate for addressing respiratory protection.

In its report "Tuberculosis in the Workplace," IOM concluded the following, with respect to fit-testing of respirators:

"Modeling studies suggest that the benefits of respiratory protection are directly proportional to the presence of risk. In facilities that admit only the occasional individual with tuberculosis or that have a policy of transferring such individuals, workers are likely to see no or very marginal additional protection from an extensive respiratory protection program."

"Administratively, a program for fit testing of personal respirators requires trained personnel to conduct a complicated series of tests... Scheduling for an annual fit test must allow time for the test as well as time for workers to get to and from the test site (which may be on another floor or in another building)...A requirement for annual retesting multiplies the number of people who must be scheduled and tested each year. The more workers who are covered by an employer's respiratory protection program, the more complex will be the employer's administrative burden and the greater the expense. For large medical centers that treat substantial numbers of tuberculosis patients, annual fit testing can be a major undertaking that involves thousands of workers."

The committee noted that, "the 1997 *Federal Register* notice of the proposed OSHA rule takes more than five pages (in small print) to describe the required fit testing procedures."

The costs of compliance as stated in the *Federal Register* grossly underestimate the true costs (page 75779). Fit-testing is extremely time consuming, labor intensive, costly and of virtually no incremental benefit when good fitting respirators are used. Since TB patients can be any age and often have other underlying disorders requiring hospital care, the feasibility of limiting fit-testing to a nominal number of workers is neither practical nor in the best interest of patient care. In addition, the majority of patients being placed in isolation do not have active pulmonary TB. Depending upon the prevalence of TB in the population served by the facility, the threshold for isolating patients, and the criteria used, the proportion of true TB cases to isolated patients has been previously reported to range from 1:7 to 1:95. In the absence of cases, the ratio cannot be enumerated. In the absence of proven benefit, this unfunded mandate is clearly unwarranted.

**4. The decision to impose this new mandate was issued on December 31, 2003 (New Years Eve) without the opportunity to review or provide public comment.**

In the December 31, 2003, *Federal Register* notice announcing the decision to apply the General Industry Respiratory Protection Standard to respiratory protection against TB, OSHA justified its decision not to provide a public comment period, by stating that evidence has already been gathered during the general respiratory protection and TB rulemaking periods. We are concerned that OSHA clearly ignored the fact that there is no scientific justification for this practice – this information was presented at the time of those rulemakings. In addition, regardless of the fact that information was gathered, it is disingenuous to later use only selected information as a justification for imposing something different than the rules for which they were originally gathered.

OSHA should address the following concerns in presenting the scientific rationale for this decision:

A. There is no evidence that respirators are necessary to control infectious diseases (due to the nature of infectious aerosols: particle size, electrostatic forces, etc.). The hierarchy of controls: early identification, prompt isolation and appropriate treatment controlled transmission of TB with the use of submicron masks (not a respirator and not fit-tested).

B. There are currently no reliable or reproducible methods of fit-testing even in a controlled setting with researchers trained to perform fit-testing. [Coffey CC, Lawrence RB, Zhuang Z et al. Comparison of five methods for fit-testing N-95 filtering-face piece respirators. *Applied Occup Environ Hyg* 2002 17(10):723-30]

C. Fit-testing is extremely labor intensive and time consuming, is of undocumented benefit, and there is no evidence that initial or annual fit-testing reflects actual in-use conditions.

D. If OSHA is going to continue to mandate respirators for health care workers with exposure to patients with potential airborne infections, then the NIOSH certification process should include a fit-testing component and publicly available rating system.

APIC is an organization whose mission is dedicated to the prevention and control of healthcare-associated infections among patients, visitors and workers. We would like the opportunity to work collaboratively with OSHA to develop sound principles and practices for prevention and control of infections and other adverse health effects. In this effort, we strongly urge OSHA to revoke this decision and/or open up the issue of the applicability of the General Industry Respiratory Protection Standard to exposure to patients with potential airborne infections. OSHA should present the scientific rationale for its decision and allow public review and comment.

If you have questions, or require further information, please contact Jennifer Thomas Barrows, Director of Government and Public Affairs, at [jthomas@apic.org](mailto:jthomas@apic.org) or 860-675-6869. Thank you for your attention to our concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Jeanne Pfeiffer". The signature is written in a cursive style with a small dot above the "i" in "Pfeiffer".

Jeanne A. Pfeiffer, RN, MPH, CIC  
2004 APIC President