

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