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New TB Respirators Expected to Save Millions

by Gina Pugliese, RN, MS,
Medical News Editor

From NIOSH

The National Institute for Occupational Safety and Health (NIOSH) announced that it has certified the first 13 respirators under its new testing and certification requirements (*Federal Register* June 8, 1995:30338). The price estimates for this first round of respirators—some as low as \$1—should mean considerable savings for the healthcare industry. "The tremendous decrease in cost is welcome news," said Human Health Services Secretary Donna E. Shalala. "In a time when regulatory actions are frowned upon, this is an excellent example of how a smart regulation can lead to considerable savings."

The new regulations, which became effective July 10, 1995, allow for a generation of respirator filters with less leakage, more efficiency, and easier breathing. Before the new regulation, the only respirator that met the filtration efficiency performance criteria outlined by the CDC for the prevention of tuberculosis cost approximately \$8. The first 13 respirators certified under the new rule will range in price from less than \$1 to \$3, according to the manufacturers. All respirators certified by NIOSH under the new

regulations will meet or exceed the CDC filtration efficiency performance criterion.

The exact savings to the healthcare industry cannot be predicted with certainty. However, a recent cost analysis of the 159 acute care inpatient Department of Veterans Affairs (VA) facilities in the US suggests that the VA alone may save up to \$16 million annually. Given that the VA system only represents a small percentage of all hospital beds in the US, the savings nationwide could be extraordinary.

NIOSH Director Dr. Linda Rosenstock said, "We are thrilled with the impact of this regulation. Working closely with industry and employee representatives has resulted in better protection for workers and increased savings for industry. It is no surprise that this activity was recognized by Vice President Gore with a Hammer Award for its impact on redesigning government."

The first 13 respirators certified under the new regulations were chosen randomly from the submissions received before the July 7, 1995, deadline. NIOSH currently is working to certify another 120 respirators awaiting approval. For information on the newly certified respirators, contact NIOSH at (800) 35-NIOSH.

From OSHA

On September 6, 1995, the Occupational Safety and Health Administration (OSHA) issued an updated enforcement policy for occupational exposure to tuberculosis in response to the recently revised NIOSH certification criteria. OSHA will accept the N-95 respirator, which meets the CDC criteria for respiratory protection, as the minimum level of respiratory protection for TB. The N-95 respirators also must be able to be (1) fit tested to obtain a face-seal leakage of less than 10%; (2) fit different facial sizes and characteristics; and (3) be able to be checked for face piece fit each time the respirator is put on. OSHA also will allow reuse of disposable respirators as long as the respirator maintains its functional and structural integrity. Each facility must have a protocol for the circumstances in which a respirator will be considered contaminated and not to be reused. OSHA notes that if a facility chooses, they may continue to use HEPA respirators.

FROM: NIOSH. NIOSH change will save healthcare industry millions. Press release, August 25, 1995.

OSHA. Update: OSHA enforcement policy for occupational exposure to tuberculosis. Memorandum, September 6, 1995.