



American College of Emergency Physicians

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July 15, 1994

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

Re: NIOSH and MSHA Proposed Requirements for Certification of Respiratory Protective Devices. RIN 0905-AB58

Dear Ms. Rosenstock:

The American College of Emergency Physicians (ACEP), a national medical specialty society representing over 17,000 emergency physicians, is pleased to provide the National Institute for Occupational Safety and Health (NIOSH) and the Department of Labor/Mine Safety and Health Administration (MSHA) with comments on the proposed requirements for certification of respiratory protective devices (42 CFR Part 84). These proposed rules will replace existing MSHA regulations with new public health regulations and also upgrade current testing requirements for particulate filters.

ACEP is concerned about the dramatic rise in tuberculosis (TB) cases in the United States. The numbers and variety of patients presenting to the emergency department (ED), and the rapid increase in the incidence of TB (particularly multi-drug resistant TB) in the United States, has resulted in an increased risk of TB transmission in the ED. Emergency departments, in particular those serving the urban poor, are a potential source of TB transmission to both health care workers (HCWs), as well as the public due to patient demographics, overcrowding, and the lack of funds for environmental controls.

Emergency departments also face the added difficulty of often treating undiagnosed cases of TB. The ability to diagnose those with TB is severely limited due to a lack of rapid diagnostic technology and the atypical clinical presentation among those also infected with HIV. Therefore, emergency physicians and other ED staff are at particular risk of contracting TB from patients with unrecognized pulmonary or laryngeal TB.

BACKGROUND

ACEP supports the recently released CDC guidelines (Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, 58 *Federal Register* October 12, 1993) that emphasize an approach to TB infection control through the application of a hierarchy of control measures. The first and most important level is the use of administrative measures to reduce the risk of exposure to persons with infectious TB.

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This includes policies and protocols to ensure the rapid detection, isolation, diagnostic evaluation, and treatment of persons likely to have TB, as well as implementing effective work practices by persons working in the health care facility. The second level is the use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei in the air.

The last level is the one that is relevant to these regulations -- the use of personal respiratory protective equipment in areas where administrative and engineering controls may not sufficiently protect persons from exposure to TB.

RESPIRATORY PROTECTION AGAINST TB

Currently, the only respirators that are certified by NIOSH and which meet CDC criteria are those with high efficiency particulate air (HEPA) filters. The College has previously stated that the mandatory use of these costly and burdensome respirators in EDs would adversely impact patient care and misuse scarce resources without sufficient evidence that they protect against TB better than other, less intrusive and costly devices.

Therefore ACEP strongly supports the efforts that NIOSH and MSHA are undertaking to upgrade certification requirements for respiratory protective devices that protect health care workers against the transmission of TB and other airborne pathogens. ACEP also supports NIOSH's replacement of their 1992 recommendations for worker protection against TB with a recommendation for use of respirators for protection against TB that meet the CDC's recommended performance criteria.

We believe that these NIOSH respirator regulations will benefit emergency physicians working in facilities that are implementing CDC guidelines. The most important outcome of these regulations is that they will ultimately enable emergency physicians and emergency department (ED) staff to select from a broader, and less costly, range of certified respirators that meet the current performance criteria recommended by CDC for respiratory devices used for protection against TB.

RESEARCH AGENDA

ACEP understands that the current regulations were developed to certify respirators used in mining and general industry, and that even the modifications to the rules were not developed specifically to certify respirators against biological agents. Therefore, the true effectiveness of these devices in preventing transmission of TB to health care workers cannot be determined because of a lack of data.

Therefore, the College urges NIOSH to support research that will enable the health care industry to understand the factors that influence the transmission of TB. We also urge NIOSH to support research that would determine the level of respiratory protection needed to protect health care workers from transmission of TB.

IMPLEMENTATION SCHEDULE

The College understands that once these NIOSH regulations are finalized, manufacturers will be able to submit applications to certify a variety of respirators that will subsequently become available to health care providers, including both disposable and non-disposable respirators, as well as powered and non-powered respirators. These other classes of air-purifying, particulate respirators are expected to be markedly less expensive than respirators with HEPA filters.

Finally, we understand that NIOSH hopes to release final regulations by the end of this year and will make them effective within 30 days of publication in order to allow for the introduction of less expensive filters as soon as possible. ACEP urges NIOSH to continue to ensure that these new regulations are placed on an accelerated implementation schedule so that the market can be expanded swiftly and users will have a broader selection of certified respirators for TB control.

Thank you for the opportunity to comment on these proposed regulations. Please do not hesitate to contact ACEP's Regulatory Representative, Roslyne D.W. Schulman at (202) 728-0610 for more information on these comments and ACEP's activities.

Sincerely,

A handwritten signature in black ink that reads "John B. McCabe". The signature is written in a cursive, flowing style.

John B. McCabe, MD, FACEP
President