



Georgia Hospital Association

1675 Terrell Mill Road, Marietta, Georgia 30067 - 404/955-0324

July 21, 1994

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

Dear Sir or Madam:

The Georgia Hospital Association (GHA), on behalf of its approximately 190 member institutions, appreciates this opportunity to provide comments on the National Institute for Occupational Safety and Health (NIOSH)'s Proposed Rule on Certification Requirements for Respiratory Protection Devices. Our understanding is that these proposed rules would replace existing Department of Labor/Mine Safety and Health Administration (MSHA) regulations with new public health regulations and also upgrade current testing requirements for particulate filters.

GHA is concerned about the dramatic rise in tuberculosis (TB) cases in the United States and the recognized risk of TB transmission in health care facilities, including the recent outbreaks of multi-drug resistant TB involving health care workers (HCWs) and patients. We continue to support efforts to protect HCWs and patients against transmission of TB.

TB Control Based on Hierarchy of Control

We believe that all TB control programs should be based on a hierarchy of controls to reduce the risk of exposure to persons with infectious TB. The first, and most important level of the hierarchy is the use of administrative controls. This includes implementation of effective protocols for rapid detection, isolation, diagnostic evaluations, and treatment of persons likely to have TB. The second level is the use of engineering controls. This involves the use of appropriate ventilation and air cleaning methods to prevent the spread and reduce the concentration of infectious droplets to protect HCWs in situations where administrative and engineering controls may not sufficiently protect persons from inhaling infectious droplet nuclei.

GHA Concerns

GHA has been extremely concerned that the only currently available certified respirators that meet or exceed the CDC's recommended performance criteria that calls for 95% filter protection at the 1.0 micron particle size are respirators with high efficiency particulate air (HEPA) filters. We recognize that the current NIOSH certification procedures for dust-mist (DM) and dust-fume-

JUL 26 1994

mist (DFM) respirators are not designed to evaluate the respirators' ability to meet CDC's performance criteria.

Implementation of the proposed regulations would provide a new category of particulate respirators, that is, "Class C" respirators, which would meet the CDC's recommended performance criteria for protection against TB. This will lead to the availability of a broader range of certified respirators for use in health-care settings that will be less costly and more practical than the HEPA respirators certified under the old regulations. GHA fully 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.

Additional Guidance Needed to Enhance Compliance at the User Level

GHA is concerned that the proposed rule does not include recommendations for the safe storage of the reusable respirator mask between uses by HCWs. GHA feels that NIOSH should address this problem in order to enhance compliance with these recommendations. The proposed rule should also address recommendations for use of the mask by family, visitors, and the patient when patients must leave the isolation room.

Finally, GHA feels that NIOSH should address the issue of employees that cannot wear the respirator mask either due to personal discomfort (they can not breathe in these masks) or due to a failed fit test. Consideration should also be given in the proposed rule to how to facilitate clearer communication with the patient while wearing the mask.

Additional Research Is Needed

We recognize that the precise level of effectiveness of respiratory protection needed to protect HCWs from transmission of TB in the health care setting cannot be determined because the data are not currently available. Moreover, the studies about the effectiveness of respiratory protection against hazardous airborne materials are based primarily on experience with respiratory protection in the industrial setting, not from *Mycobacterium tuberculosis*. Therefore, we urge NIOSH to support research that will enable us to fully understand the factors that influence the transmission of TB and the level of effectiveness of respiratory protection necessary to protect HCWs from transmission of TB.

GHA Supports Rapid Implementation of Regulations

We applaud NIOSH for taking the necessary steps to overcome the regulatory obstacles for developing new procedures for testing and certifying respirators and upgrading current respirator requirements. The modular approach to this rulemaking process will expedite the changes in testing procedures and provide the opportunity to incorporate the best available scientific information and expertise into each regulatory module. We are pleased to see that the first module will improve the current approach to testing and certifying air purifying respirators with particulate filters, the category of respirators used for protection against TB. In this era of health care reform and fixed resources, this new generation of respirators is urgently needed to

protect HCWs against TB and to hold down the cost of providing quality health care.

The proposed standard is an important first step in improving the certification process for respiratory devices for protection against TB and other biologic hazards in the health care setting. There is a need for a certification process that addresses the CDC's performance criteria for respiratory protection against TB that should be acceptable for most HCW needs. It is urgent that these new testing and certification procedures be implemented soon to open up the market for more practical and economic respiratory protection for HCWs against TB.

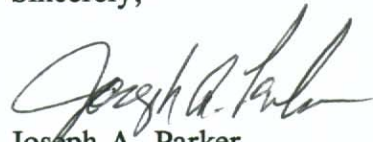
GHA urges NIOSH to place these new regulations on an accelerated implementation schedule so that the market can be expanded swiftly and users will have a broader selection of certified respirators for TB control.

Conclusion

GHA supports measures to control the transmission of TB in health care facilities and protect HCWs and patients. We believe that prevention and control of TB is vital to public health and, toward that end, GHA continues to provide our members with information in prevention and control of TB through teleconferences and other educational resources.

Once again, GHA applauds NIOSH for its work on this proposed rule and for the opportunity to submit our comments on this important issue.

Sincerely,



Joseph A. Parker
President