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**Statement of the American Hospital Association
on
NIOSH's Proposed Rule on Respiratory Protection Devices
at the
NIOSH Informal Public Hearing
June 23-24, 1994**

Introduction

My name is Gina Pugliese and I am the Director of Infection Control and Environmental Safety at the American Hospital Association (AHA). I am here today on behalf of the AHA and its more than 4500 member institutions to comment on the proposed rule that addresses the National Institute for Occupational Safety and Health's (NIOSH) and the Department of Labor/Mine Safety and Health Administration's (MSHA) certification requirements for respiratory protection devices. Our understanding is that these proposed rules would replace existing MSHA regulations with new public health regulations and also upgrade current testing requirements for particulate filters. These comments represent those of the AHA's Technical Panel on Infections Within Hospitals in collaboration with AHA staff experts in infection control and occupational safety and health.

The AHA 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 droplet nuclei in the air. The third level of the hierarchy is the use of personal respiratory protection to protect HCWs in situations where administrative and engineering controls may not sufficiently protect persons from inhaling infectious droplet nuclei.

Summary of AHA's Concerns

The AHA has been concerned that respirators with high efficiency particulate air (HEPA) filters are required because these are the **only** currently available certified respirator that meets or exceeds the CDC's recommended performance criteria that calls for 95% filter protection at the 1.0 micron particle size.¹ We recognize that the current NIOSH certification procedures for dust-mist (DM) and dust-fume-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.

In addition, the AHA fully supports NIOSH's replacement of their 1992 recommendations for worker protection against TB² with a recommendation for use of respirators for protection against TB that meet the CDC's recommended performance criteria.¹

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.

AHA Supports Swift 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.

We urge 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

The AHA is committed to supporting measures to control the transmission of TB in health care facilities and protect HCWS and patients. We recently conducted a survey of hospitals, in collaboration with CDC, to assess the status of TB infection control programs in U.S. hospitals. The results of this survey will be used to identify those areas where further emphasis and additional resources may be needed. We believe that prevention and control of TB is vital to public health and, toward that end, the AHA continues to provide our members with state-of-the-art information in prevention and control of TB through technical briefings, teleconferences, and other educational resources.

We have shared this proposed rule with our member hospitals and encouraged them to send written comments to NIOSH in support of the proposed standard as an important first step in improving the certification process for respiratory protection devices for protection against TB and other biologic hazards in the health care setting.

We appreciate the opportunity to share our views. Thank you

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1. CDC. Draft Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, Second Edition; 58 *Federal Register* pp 52810-52854; October 12, 1993.
 2. NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health Care Facilities Potentially Exposed to Tuberculosis. September 14, 1992.