Statement of the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)
on
NIOSH's Proposed Rule on Respiratory Protection Devices

at the NIOSH Informal Public Hearing July 24, 1994

Good Morning. My name is Jacalyn Bryan and I am here today to testify for the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC). APIC is a multidisciplinary organization of over 10,000 health care professionals who practice institutional epidemiology, quality improvement, and infection control in a variety of health care settings throughout the United States. One of our primary roles is to develop and implement sound scientific strategies for protecting our patients, staff, and the public from acquiring infectious diseases. Our profession relies on scientific data and epidemiologic methods to prevent disease transmission. We support all efforts to promote standards of prevention which are scientifically sound, realistically achievable, and which service all who encounter the health care environment including patients, workers, students, and persons from the community. We welcome the opportunity and are pleased to respond to NIOSH'S Proposed Rule on Respiratory Protective Devices (42CFR Part 84 Federal Register Vol 59, Page 99, pp26850-26893).

In September of 1993 APIC responded to OSHA's request for comment on the proposed enforcement policy and procedures for occupational exposure to tuberculosis. One of the major concerns we expressed in response to OSHA's proposed enforcement policy was the lack of sufficient data to support the HEPA particulate respirator mask as a minimum and universal standard for respiratory protection against TB. The move to such a standard would impose an inappropriate burden on personnel, material, and fiscal resources. We have stressed that the

scientific support for these devices in non-existent. Respiratory protection has always been acknowledged to be the least important element in the OSHA supported hierarchy of prevention that relies on early identification of infected cases and implementation of engineering controls as primary prevention strategies. There now is sufficient scientific evidence to suggest that when primary prevention strategies are implemented, transmission is interrupted. For example, at the APIC Annual Educational Conference held in May of 1994 in Cincinnati, Ohio, representatives from the Centers for Disease Control and Prevention (CDC) announced that the outbreaks of Multi-drug Resistant Tuberculosis which were widely reported in the media had returned to previous baseline rates. This was accomplished primarily by implementing the requirements of the 1990 TB guidelines published by the CDC. These guidelines did not include the use of special high efficiency particulate air (HEPA) filtered respirators. Early diagnosis, treatment, and directly observed therapy were the interventions that had the greatest impact in quelling these outbreaks. This finding was predictable.

We are concerned that the disproportionate focus on respirators for controlling occupational exposure to TB created an erroneous impression that respirators are the primary intervention for health care worker protection. The concerns that we have previously expressed remain and are documented in responses to OSHA and CDC. However, we support NIOSH's proposed rule because it allows manufacturers to develop a broader ranges of respirators which meet the CDC's performance criteria as outlines in the 1993 proposed TB guidelines. This proposal essentially removes the earlier impractical NIOSH recommendation to use Powered Air-Purifying Respirators (PAPRs) and allows options other than the current OSHA-mandated HEPA particulate respirator (PR). In essence, it is a step forward in developing a more scientific

approach to the prevention of occupational exposure to TB. We feel that the new NIOSH performance standards will provide a fair and reliable way of evaluating PR use in the future. APIC recognizes that the certification process finally addresses the health care setting and that "Class C" filtered respirators with a 95% filtration efficiency should be acceptable for most health care worker needs. We also recognize that fit testing programs will still be required, but the total program should be less costly as a broader range of certified respirators are made available in the marketplace. In addition, we would expect fewer usage problems and greater comfort to the health care worker. Infection Control Professionals have an equal concern for both patient and employee protection and well being. A science-based usage requirement will enable support for a more consistent approach to prevention of TB among all populations. We would also like to encourage manufacturers of these devices to not only design safe and effective PRs, but to assure that are non-allergenic and can be worn by persons who wear glasses. For these reasons we support the proposed standard and encourage NIOSH to continue using scientifically valid strategies for the prevention of occupational TB. This new generation of respirators is urgently needed and for this reason we urge NIOSH to place implementation of these new regulations on a "fast track" so the market can expand quickly and users will have a broader selection of certified respirators for TB control.

APIC has shared this proposed rule with our membership 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 and the protection of health care workers from occupational exposure to TB.

Thank you for the opportunity to share our views.