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Dear Sirs

We are writing in response to the National Institute for Occupational Safety and Health's (NIOSH) request for written comments in 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule (*Federal Register*/Vol. 59, No. 99/Tuesday, May 24, 1994). These comments represent the position of the Association for Professionals in Infection Control 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. The professionals represented by APIC are ultimately responsible for administrating, facilitating, and implementing strategies designed to prevent infectious disease transmission to patients and staff within health care facilities. As such they will be responsible for implementing any respiratory protection program which is aimed at the prevention of occupational tuberculosis (TB) transmission. This includes the training of employees and any required fit-testing of respiratory protective devices designed to prevent occupational exposure to TB. The organization and its members pride themselves in developing and implementing sound strategies based on scientific data and epidemiologic methods to protect patients, staff, and the public from acquiring infectious diseases. As an authority in this area, APIC has been actively monitoring and providing input into the debate regarding the appropriate scientific response to the risk of TB transmission. As stated in APIC's oral testimony at the informal public hearing on the proposed rule for the certification of respiratory protective devices, APIC supports 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. APIC welcomes the opportunity to respond in writing to NIOSH's request for comments.

The recently published Centers for Disease Control and Prevention's (CDC) proposed Guidelines for Preventing the Transmission

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of Tuberculosis in Health Care Facilities (*58 Federal Register/pp 52810-52854/October 12, 1993*) acknowledged that most cases of tuberculosis transmitted within health care settings occur because of employee exposure to undiagnosed cases of TB. For this reason, it is unlikely that the use of respiratory protective devices will have a significant impact on reducing the rate of acquisition of occupational TB. Our major emphasis must be placed on early diagnosis and treatment, so that prompt isolation and appropriate therapy can be undertaken. In the past, APIC has responded to the Occupational Safety and Health Administration's (OSHA) request for comment on the proposed Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis. One of the primary concerns APIC expressed in response to OSHA's enforcement policy was "there is insufficient data to support the high efficiency particulate air (HEPA) filtered 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, materiel, and fiscal resources." (APIC Comments on the Occupational Safety and Health Administration's October 18, 1993, "Enforcement Policies and Procedures for Occupational Exposure to Tuberculosis", September 24, 1993) We have stressed that the scientific support for these devices is nonexistent. These concerns are supported in a recent paper published in the *Annals of Internal Medicine* (1994; Vol. 121: 37-40) entitled Tuberculosis Control Strategies: The Cost of Particulate Respirators. As stated by the authors in the conclusion of the paper "Optimally, funds should be set aside to investigate the efficacy of proposed regulations so consumers can know the value of their investment." The need for, and the efficacy of particulate respirators for the protection of health care workers from transmission of TB in the health care setting remain a concern to APIC's membership. Therefore, APIC encourages NIOSH to support much needed research into the precise level of respiratory protection necessary to protect health care workers from transmission of TB. Additionally, 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 is now 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 CDC announced that the outbreaks of the Multi-drug Resistant Tuberculosis (MDRTB) 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 HEPA-filtered respirators. Early diagnosis, treatment, and observed therapy were the interventions that successfully

controlled these outbreaks. This finding was predictable and stated in APIC's comments to OSHA.

APIC continues to be concerned that the disproportionate focus on respirators for controlling occupational exposure to TB has created an erroneous impression that respirators are the primary intervention for health care worker protection. The concerns APIC previously expressed remain and are documented in an attached copy of our response to OSHA (Attachment A). However, APIC supports NIOSH's proposed rule because it allows manufacturers to develop a broader range of respirators which meet the CDC's performance criteria as outlined in the 1993 proposed TB guidelines. This proposed rule essentially removes the earlier impractical NIOSH recommendation to use Powered Air-Purifying Respirators (PAPRs) and allows options other than the currently OSHA-mandated HEPA-filtered particulate respirators (PRs). In essence, it is a step forward in developing a more scientific approach to the prevention of occupational exposure to TB. APIC believes the new NIOSH performance standards will provide a fair and reliable way of evaluating the efficacy of any PRs in the future. APIC recognizes that the certification process finally addresses the health care setting and the Type C filters with a 95% filter efficiency at 1.0 micron should be acceptable for most health care worker needs. APIC recognizes that fit testing/checking programs will still be required but at less cost. In addition, fewer usage problems and greater comfort for the health care worker would be expected. For these reasons, APIC supports the proposed standard and encourages NIOSH to accelerate implementation of the proposed rule as it supports scientifically valid strategies for the prevention of occupational TB.

APIC appreciates the opportunity to share its perspective with NIOSH.



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