



July 22, 1994

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

Dear Sirs:

I am writing to provide comments on your recent proposed rule covering Respiratory Protective Devices (42 CFR Part 84) as published in the Federal Register (Vol. 59, No. 99, Pages 26850-26889) on Tuesday, May 24, 1994. These comments are provided on behalf of Catherine McAuley Health System, a 788 bed, three hospital consortium, that is a regional community teaching health system. I will be limiting my remarks to the use of particulate respirators (PRs) in health care facilities for protection against biological agents, i.e. Mycobacterium tuberculosis.

I. GENERAL COMMENTS

- A. The issue of use of PR's by health care personnel has only recently been raised in response to a recommendation for their use by the Centers of Disease Control & Prevention (CDC) in their 1990 Tuberculosis Prevention Guidelines (1). This occurred despite the acknowledgment that the efficacy of PRs in protecting susceptible persons from infection with TB was not documented (1). These guidelines and a subsequent draft, however, emphasized that in the hierarchy of TB control measures, early identification and treatment of patients with TB disease plus environmental engineering measures are first and second priorities, respectively, to interrupt transmission of TB (1,2). This has also been the position of the several other professional associations with expertise in TB epidemiology/control (3,4). I feel this point is needs emphasis when discussing respiratory protection for health care workers (HCWs).

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- B. Given the lack of scientific evidence for PRs, I would submit that many other measures which include source identification, directly observed therapy (DOT), and proper isolation practices are much more important than use of PRs (5). Indeed, data presented at a recent TB symposium highlighted that implementation of the CDC's 1990 TB Guidelines promptly controlled nosocomial outbreaks in several major cities (6,7). In particular, one of these outbreaks was brought under control without the use of PRs (7). Indirectly, there is evidence that in 1993 the cases of TB in the U.S. has begun to decline for the first time since its resurgence in the mid-1980s (8). This decline is probably a function of DOT and enhanced case identification and management. It remains to be seen whether this trend will continue. However, I doubt if PRs were in use in a majority of facilities in 1993 and therefore accounted for any measurable impact on TB transmission. Again, the evidence points to administrative and engineering controls as overwhelmingly critical to TB control.
- C. While NIOSH is prohibited from cost-effective analysis of measures used to prevent occupational exposure, I think it is important to consider two recent analyses which arrived at very similar conclusions. Dr. Adal and others conducted a cost-effective study of the high efficiency particulate air (HEPA)-PR which is currently enforced by OSHA for respiratory protection of HCWs against TB. They found the cost of preventing a single case of occupational TB over the next 41 years using a HEPA-PR ranged between \$1.3 to \$18.5 million dollars at their institution alone (9). Nettleman, et al, also examined this issue using a questionnaire administered to 159 VA Medical Centers. The cost of HEPA-PRs equated to \$7 million dollars per case of TB prevented and \$100 million dollars per life saved (10). Such extraordinary expenditures are detriments to the survival of the health care industry, especially in light of ongoing reform. In addition, there is scientific evidence that high efficiency masks, which would not require a respiratory protection program, filter as well as PRs (11).

In light of the above, I am encouraged and support this proposed rule containing filter standards for particulate respirators (Subpart K). It addresses the unique needs of the HCWs in the clinical environment of a health care facility and will allow facilities flexibility to comply with CDC Guidelines (2) without sole reliance on the HEPA-PR for protection of HCWs. The evidence above strongly suggests there has been too much energy expended on the PR issue for hospitals and any change in regulatory requirements for these devices is welcomed.

II. SPECIFIC COMMENTS

- A. Subpart K - Particulate Respirators (Federal Register, Pgs 26883-26885) - I support the listed performance requirements for certifying air purifying respirators. As identified in the "Background" information of this proposal rule, Type A, B, or C filters will fulfill performance criteria in the 2nd edition of the CDC TB Guidelines (2). I concur with this move and urge prompt adoption of the new rule as expeditiously as possible.

Thank you for the opportunity to comment on this proposed rule.

Sincerely yours,

A handwritten signature in cursive script, reading "Russell N. Olmsted". The signature is written in dark ink and extends across the width of the page.

Russell N. Olmsted, MPH, CIC
Epidemiologist, Infection Control Services

cc: Mine Safety and Health Administration

REFERENCES

1. CDC Guidelines for preventing the transmission of tuberculosis in health-care settings, with special focus on HIV-related issues. MMWR 1990; 39 (RR-17): (inclusive page numbers).
2. CDC Guidelines for preventing transmission of tuberculosis in health-care settings. 2nd edition, Notice of comment period. Federal Register, October 12, 1993; 58: 52810-52854.
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6. Dooley SW. Epidemiology of TB and drug-resistant TB in the U.S. APIC TB Symposium, Tuesday, May 24, 1994, APIC '94, Cincinnati, OH.
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9. Adal, KA, et al. The use of HEPA-filter respirators to protect hospital workers from TB. NEJM 1994; 331: 169-173.
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11. Chen S-K, et al. Evaluation of single-use masks and respirators for protection of HCWs against mycobacterial aerosols. Am J Infect Control 1994; 22: 65-74.