July 20, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4678 Columbia Parkway
Cincinnati, OH 45226

RE: RESPIRATORY PROTECTIVE DEVICES
42 CFR Part 84 Federal Register, Volume 59, No. 99,
pp 26850 - 26893

1. I support this first step in improving the certification process. It is critical to me as a health care worker, and an infection control practitioner that the certification of respiratory protection devices be based on scientifically valid data. To date I have been unable to find any such data to support the use of Powered Air-Purifying Respirators.

2. The premise upon which NIOSH operates, that of zero risk exposure is not an acceptable base to build regulatory statements for health care application. Again, I can find no scientific data that states exposure to one tubercle bacillus will result in infection. The health care industry cannot afford to knee jerk a response that is costly, of no proven efficacy and labor intensive.

3. A filtering capacity of 95% should be adequate to protect the health care worker. With the review, updating and improvement of the NIOSH certification process masks that have been proven clinically to be effective in preventing transmission of tuberculosis can be approved.

4. The unresolved issues of storage between use, reuse, and length of use for hepa filter respirators must be resolved before promulgating such a standard.

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5. It is important to note that no other drastic and incredibly costly change has ever been brought into the health care arena without pre-testing and on-site testing. OSHA, for this reason, and the above reusing must be asked to suspend this recommendation pending testing on-site and changes in the certification process.

6. Infection Control Professionals, from the very beginning of their existence have been committed to the reduction and avoidance of transmission of disease to patients and employees. The acquisition of occupationally acquired tuberculosis is indeed a frightening thought to all of us in the health care arena.

Cost effective measures, scientifically valid measures (not what NIOSH is currently saying) are essentials in the health care arena of the 90’s when everyone of us "in the trenches" is dealing with diminishing resources, increasing regulatory requirements and a sicker, largely under or non-insured population.

7. Finally squandering of precious health care resources in the fulfillment of regulations with no scientific validity is reprehensible. The money would be better spent on tuberculosis screening measures, proven methods of tuberculosis control.

8. You will note there has been no support forthcoming from infection control practitioners, infectious disease physicians, hospital epidemiologists or pulmonary physicians for the CDC/OSHA recommendations for hepa filter respirators.

Thank you for the opportunity to respond.

Yours truly,

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Infection Control Department
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cc: Congressman Michael Huffington (R)
J. Bryan, Chairperson, GAC, APICE, Washington D.C.
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