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AMERICAN THORACIC SOCIETY

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To Whom It May Concern:


The enclosed comments are those of the American Thoracic Society in response to the NIOSH notice of May 24, 1994, as printed in the *Federal Register*, Vol. 59, No. 99.

The American Thoracic Society (ATS) is a professional organization of over 11,000 physicians, scientists and other health care professionals who specialize in pulmonary medicine and lung-related research. The ATS also serves as the medical section of the American Lung Association.

Overall, the ATS members who reviewed this document were impressed with the scientific content of the document. However, our reviewers had several concerns about the document in its present form. These concerns are contained in the attached document.

The ATS would be happy to provide further comments on the issues contained in future related guidelines, or provide further clarification of our concerns. Please contact Judy Corn at (212) 315-8709 or Andrew Prescott at (212) 315-8728 in the ATS New York Office for assistance.

Sincerely,


Gary W. Hunninghake, M.D.
President, American Thoracic Society

Medical Section of



Official Journals
American Journal of
Respiratory and Critical
Care Medicine

American Journal of
Respiratory Cell and
Molecular Biology

cc: Philip Harber, MD, MPH
Scott Weiss, MD
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American Thoracic Society

Comments on the NIOSH Proposal "Respiratory Protective Devices"

1. The fundamental change proposed-- characterizing respirator filtration efficacy by particle size and type rather than by specific chemical agent type-- is long overdue. However, there are several implicit assumptions upon which this approach rests. Unfortunately, the material published in the Fed Register does not document that there is adequate experimental support for these. The assumptions may be subject to relatively simple empiric validation using experimentally generated aerosols. Therefore, there is a need to review this change in the future.
The assumptions are:
 - a. That bioaerosols, particularly M tuberculosis, are handled comparably to particulates. This should be empirically tested.
 - b. That mass mean aerodynamic diameter adequately characterizes particles from the standpoint of filtration efficiency and that particle shape and charge differences will not effect protection factors. For example, it is necessary to confirm that a filtration efficiency determined with uncharged spherical particles will be directly applicable to fibers (eg., asbestos, fibrous glass).
2. The level of exercise in paragraph 84.182 (b) (2) should be specified. The airflow resistance tests (para 84.183) should be performed at air flow rates greater than 85 l/min since this value is lower than instantaneous values actually employed by workers in many jobs.
3. The fit test procedures (isoamyl acetate detection) includes a significant subjective component. In addition, facial configuration and other factors will affect this. Therefore, the regulation should state explicitly that it must be performed by an adequate number of subjects who differ in facial configuration/size. (The latter requirement can be met by assuring that both sexes and subjects with adequate range of body weight are included).
4. NIOSH should be requested to investigate alternatives to this subjective qualitative method for assessment. For example, a mask modified with a probe for quantitative fit testing (eg., by PortaCount technique) should be considered.

The adequacy of considering fit in actual use rather than reliance upon penetration through filter medium per se is of considerable import. A significant leakage occurs around rather than through the filter medium, and certification of respirator designs which encourage such leak may lead to worker overexposure.

5. Provision should be made for respirators with lower efficiencies than the least effective of the three categories described. Otherwise, employers who provide respirators for nuisance dust only or for larger particle size dust may be accused of using non-approved equipment. (OSHA requires that all respirator users be in an approved program, even if the purpose for use is relatively optional).

In summary, the proposed changes will update the certification criteria and will significantly decrease the cost of providing adequate respiratory protection to health care and other workers. However, there is a need to explicitly recognize the assumptions and conduct further research.