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Linda Rosenstock, MD, Director
c/o NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Dr. Rosenstock:

I would like to comment on NIOSH's proposed revisions to the respirator testing and certification regulations (new 42 CFR part 184), which were published in the *Federal Register* Vol. 59, N. 99, pp. 26850-26889, May 24, 1994. According to the CDC Office of General Counsel, these comments will be considered.

As chair of the ANSI Z88.12 committee on Respiratory Protection against Infectious Aerosols, I choose to comment specifically on the reclassification of respiratory protective equipment (RPE) for dust/mist/fume contaminants to Types A, B, and C because this affects RPE selection in healthcare to prevent respiratory exposure to MTB.

The assigned protection factor (APF) of an air-purifying respirator cannot be divorced from the filtration efficiency of the filter media. Just because filters are rated for their efficiency in capturing particles does not automatically mean that classes of air-purifying respirators reduce the exposure to or below an acceptable level of risk for any particulate airborne contaminant at any concentration. As you well know, an APF is based on the overall design and function of the class of respirator.

There is absolutely no data that documents the level of protection (and hence, the APF) required to provide adequate respiratory protection from MTB. No data exists that says unequivocally any one respirator class, or filter within a class for that matter, will adequately protect the wearer. Historical, theoretical, or actual data regarding the size of MTB and filtration efficiencies of filter media have *nothing* to do with the degree of the hazard. Evaluation of the nature of the hazard is a basic concept historically supported by NIOSH, ANSI, and OSHA, which implies quantitation of the degree, or intensity, of the exposure, and, which must be considered in the selection of RPE. It is not apparent that NIOSH has incorporated this basic concept in the new classification of particulate filters. How can basic principles of respiratory protection be ignored in the haste to promulgate 42 CFR?

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Knowledgeable health and safety professionals can presently recommend classes of respirators despite the lack of breathing zone sampling data by predetermining an acceptable level of risk. The very RELs and PELs which NIOSH and OSHA established, respectively, inherently contain an acceptance of risk. How can NIOSH ignore or postpone such a risk assessment presumably because the industry involved is not a "traditional" industry, such as the steel industry. The kneejerk reactions of the healthcare industry to CDC's 1990 disposable dust/mist air-purifying respirator recommendation and subsequently to NIOSH's tiered respirator recommendations, demonstrate that it does not view itself subject to the same tenets of occupational health and safety as all other industries. By ignoring basic principles of respiratory protection, NIOSH is sending all industry the message that healthcare is uniquely different and operates on different principles of health and safety.

In summary, the national debate over the filtration efficiency of filter media has diverted attention from the most important question of how much protection is needed from a respirator in terms of the level of exposure and the overall design and fit of the respirator. NIOSH should not support any reclassification without establishing an acceptable level of risk of tuberculosis.

Thank you for this opportunity to comment. Please feel free to contact me with any questions or comments you might have at 415-359-4352.

Patricia Heinsohn

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