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July 21, 1994

Ms. Diane Manning
 Docket Officer
 NIOSH Docket Office
 Centers for Disease Control
 and Prevention
 Robert A. Taft Laboratories
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 4676 Columbia Parkway
 Cincinnati, OH 45226

Sent Via USPS
Overnight Mail:
 EF451431986US

SUBJECT: Commentary Regarding DHHS/PHS Proposed
 Rule 42 CFR Part 84, as Published in the
 May 24, 1994 Federal Register; RIN 0905-AB58

Dear Ms. Manning:

Please enter this commentary into the docket for module one, Particulate Filter Tests, for the subject document (above).

Section II, Background, Columns 1 and 2, page 26852:

Strong questions remain whether or not non-HEPA filter media will successfully capture various size particulates, especially sub-micron sized particles. Based upon evidence presented in CDC's September 14, 1992 (NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis) and September 15, 1992 (A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists) documents, these explain how existing non-HEPA filter media will not successfully capture TB bacterium. Additionally, page 41 of the first referenced document (above) clearly specified PAPR's with HEPA filters or airline systems as minimum acceptable respiratory protection. Finally, any attempt to perpetuate the belief DM or DFM filter media will be \geq HEPA filter media in filtration efficiency is totally misdirected. The revised criteria (A,B,C types) may not ensure the B and C versions filtration efficiencies for TB provide sufficient protection.

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Subpart H, Section 84.104, page 26871:

A QNFT is hereby recommended versus the specified OLFT. The specific test exercises and pass/fail criteria (overall protection factor [OPF] and a minimum score for each exercise) needs to be established. Consistent with recommendations in published literature, the minimum OPF may be established at 10,000.

Subpart I, Section 84,124, page 26875:

Appropriate QLFT and QNFT test exercise protocols and pass/fail scoring criteria still need to be developed for mouthpiece [escape] respirators. Yet, is this practical or technically feasible? I am uncertain.

The four test exercises specified in (e) (3) may eventually prove valid for mouthpiece respirators; for facepieces they are unsuitable to satisfactorily evaluate facepiece leakage characteristics. Specifically, these exercises do not stress the face-to-facepiece seal like the "traditional" exercises such as the properly performed SS, UD, RB, etc. The specified exercises will undoubtedly increase the cardio-vascular breathing cycle. Unless the facepiece is purposely stressed via the UD, RB, etc. - the testing has failed to meet its intended purposes.

Subpart J, Section 84.159, page 26881:

The same basic commentary regarding the unsuitability of non face-to-facepiece seal stretching test exercises is presented. The properly performed SS,UD, RB, etc. test exercises need to be utilized.

Are there valid reasons only two exercises of five minute duration are being specified?

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Subpart K, Section 84.205, page 26887:

Identical commentary as provided for Subpart I, Section 84.124, is submitted for this Subpart.

OTHER COMMENTARY

Attributable to many person's years of improper respirator and/or filter media selection¹, my strong recommendation is serious consideration be given to allowing only one type particulate filter media. This would eliminate an element of potential respirator misuse (i.e. incorrect filter selection). The allowable media would be, namely, the HEPA type.

Consideration should also be towards raising our HEPA standard to 99.9999% efficiency as specified in several European respiratory standards.

Those of us in the ES&H professions are duty bound to protect lives and property. Every effort must be made towards that end; there should be no debate about implementing sound protective measures. Since personal protective devices are the last line of defense, they must be the best we can produce. If this means a few more million dollars will have to be spent, so be it. Society can either pay now, or later. In the instances of occupational exposures, too often individuals pay later - with prematurely shortened lives or reduced life quality.

Lastly, my apologies are offered for the brevity of commentary and/or writing style clarity. Severe time constraints have limited my input on this module. Future commentary will be more focused.

¹ Specific examples include persons using DM/DMF respirators for asbestos or lead working activities.

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Should there be any questions or concerns, please contact the undersigned.

Respectfully,

Lawrence R. Gretz
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