

ISEA Industrial Safety Equipment Association

October 22, 1992

Ms. Diane D. Porter
Assistant Director for Legislation and Policy Coordination
National Institute for Occupational Safety & Health
Centers for Disease Control
Atlanta, GA 30333

Dear Ms. Porter:

This letter provides additional comments from the Industrial Safety Equipment Association (ISEA) to the National Institute for Occupational Safety and Health (NIOSH) on the proposed activities of the NIOSH Technical Review Panel. We welcome the opportunity to work with NIOSH on this effort and look forward to a continuing, constructive relationship.

We understand, the Panel will be asked to review the scientific basis for the draft assigned protection factors (APFs) in NIOSH's September 15, 1992 draft document, *"A Performance Evaluation of DM and DME Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists."* In an effort to be constructive in this review process, ISEA suggests the Technical Review Panel address several issues raised by the draft document. We believe NIOSH would benefit significantly by the Panel's review of these issues as they provide the major underpinning of the agency's draft conclusions on APFs in the document. Specifically,

- NIOSH is basing its assessment of respirator performance using a monodisperse, worst case size, test aerosol to judge respirator performance in actual use. Since every reference in the published literature describes dusts found in workplaces to have particles in sizes varying over several orders of magnitude, is it appropriate to use a monodisperse model to evaluate how the respirator will actually perform in the workplace?
- NIOSH is assessing worker exposure to airborne particulates while wearing a respirator based on particle counts and not the mass of the substance. With the exception of fibrous materials, such as asbestos, all NIOSH Recommended Exposure Limits (RELs), OSHA Permissible Exposure Levels (PELs), ACGIH Threshold Limit Values (TLVs), Ceiling Limits, and Short Term Exposure Limits (STELs) are based on the mass of the substance and not the number of particles of the substance that a worker is exposed to. Since the purpose of measuring respirator performance is to ensure acceptable worker exposures, is it appropriate to measure performance based on particle count instead of mass?

- NIOSH is assuming that half mask respirators with an assigned protection factor of 10 will have 10% face seal leakage and that assigned protection factors are based only on face seal leakage. Fit factors are the measure of face seal leakage. Assigned protection factors take into account total inward leakage of the respirator. This includes face seal leakage and filter penetration. The ANSI Z88.2 1992 national consensus standard states that the fit factor must be 10 times greater than the assigned protection factor. Likewise all the OSHA standards promulgated in the last decade require respirator fit factors at least ten times higher than the assigned protection factor before a respirator would be judged to have adequate fit and may be assigned to a worker. Is NIOSH's assumption of 10% face seal leakage for a half mask correct?
- NIOSH uses the Upper Confidence Limit in this document to describe the true level of respirator performance. In addition to the 1 sided 95% upper confidence limit that NIOSH reports as the true statistical level of respirator performance, there is a 1 sided 95% lower confidence limit that is equally valid in predicting failure rates of the respirators evaluated in the workplace protection factor studies. In simpler terms what should be described is a prediction of worst possible case situation and a best possible case situation. Logically, the condition that is most likely to occur in the real world is somewhere between those two extremes. Should NIOSH report and base its decisions on a complete analysis of all the available information rather than that portion describing the worst case?
- NIOSH is discounting all the workplace data on respirator performance. NIOSH, in one of their own peer reviewed unaccepted studies, supposedly found that corrections were needed to account for test errors that could occur because of sampling probe bias, lung deposition, and filter holder wall deposition. While in some cases, these test errors may overestimate the workplace protection factors found, they will also underestimate the protection factors found generally balancing the estimate. Should NIOSH have discounted the nine studies because these corrections were not made?
- NIOSH is assuming that every half mask respirator with an assigned protection factor of 10 will be used at 10 times the PEL. This is not true in many workplaces where half mask respirators are used. Ten times the PEL is the maximum use concentration of a hazardous particulate in which a half mask respirator can be used. The exposure levels that workers are exposed to are log normally distributed. If ten times the PEL is the upper limit that a respirator can be used, then the median level of worker exposure will be around 2 times the PEL. Is the use of the Maximum Use Concentration for a respirator the appropriate level to calculate the number of workers that will be overexposed while wearing that respirator?

- NIOSH also assumes that current validated fit test methods used to assess the fit of a respirator before the respirator is assigned to an individual are inadequate and not able to assess respirator fit. Is this correct?
- Table D on Page 11 of the NIOSH draft report contains a footnote D that is not in the ANSI standard. The inclusion of this footnote by NIOSH misrepresents the intent of the ANSI standard. This fictitious footnote is used to support the NIOSH arguments used in Section 16 as to why the ANSI recommendation regarding filter selection is infeasible. What the ANSI standard does say regarding particle size and filter selection is:

Section 6.2.2.1 (6) Determine the physical state of the contaminant. If an aerosol, determine or estimate the particle size. (underline added)

Section 6.2.2.2 (10) If the contaminant is an aerosol, with an unknown particle size or less than 2 um (MMAD), a high efficiency filter shall be used.

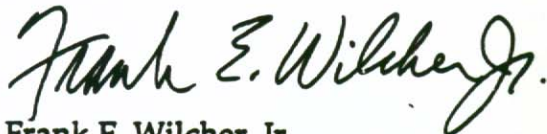
Section 6.2.2.2 (12) If the contaminant is an aerosol, with a particle size greater than 2 um (MMAD), any filter type (dust, fumes, mist or high efficiency) may be used.

Numerous technical papers have successfully estimated and measured the particle size for various workplace processes. Is it reasonable to estimate the particle size in the workplace for various manufacturing operations? Is the ANSI method reasonable for filter selection?

ISEA remains committed to assisting NIOSH in its efforts to propose a scientifically sound rule on respirator certification that considers real world workplace experience and addresses the economic realities of both manufacturers and users of respirators.

If you have any questions about the information provided, please do not hesitate to contact me.

Sincerely,



Frank E. Wilcher, Jr.
President

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