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Ms. Diane D. Porter
National Institute for Occupational
Safety and Health
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Dear Ms. Porter:

I have reviewed the NIOSH draft document entitled, "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists" and the ISEA review of this draft document. My overall evaluation is that the NIOSH authors drew their conclusions and then gathered data to support these conclusions. If this is not the case, then the draft should be rewritten to avoid giving the reader that impression. This impression is evident throughout the draft and was very disturbing. It distracted my attention from the supporting information.

Another problem I found with the draft is that I had a hard time following the train of thought. I frequently thought that I knew where a section was leading, only to find that the conclusion was somewhat of a surprise. I admit that this problem may be my own ability to understand what the authors were saying rather than the logical sequence of what was being said.

I also had trouble with the way the authors dismissed certain data and accepted other data. Again, it seemed that if a study supported their conclusions, it was valid. All others would be discounted. The ISEA points this out in their review, and although I am not entirely in agreement with the ISEA review, it does point out some significant flaws in the draft.

As you requested, I would like to address the five specific areas in which you were interested.

1. "The explicit and implicit assumptions supporting the evaluation;"

   I have some trouble dealing with this one because of the overall impression that I have of the conclusions preceding the evaluation. This overall impression has led to my believing that the explicit and implicit assumptions can all be summed up as: We must lower the APFs for these respirators! Now let's go get the data to support his action.

2. "the four independent research studies on filter leakage which provided the data on which the evaluation is based;"

   I only had access to the published results from Hinds and Kraske and Willeke and Chen. The other two studies were reported to NIOSH and are not published. Also, most of the data used from Hinds and Kraske is in a letter to NIOSH, not in their published paper. Since the information in these four studies is crucial to accepting or rejecting the NIOSH conclusions, it should have been provided to the reviewers. What I was able to review appears to support the NIOSH conclusions. However, it does this only because NIOSH presented the data, in a convincing, rather than objective way. Plotting particle diameter vs. leakage or protection factor is very dramatic though of limited use from a worker protection standpoint. Although ISEA slanted their presentation of the same data by insisting on using a PF of 100 for half-mask respirators, their use of particle diameter vs. cumulative mass is better related to dose of the contaminant to the worker. Neither evaluation adequately addresses retention in the respiratory tract which I believe should have been considered.

3. "the criteria by which data were selected from these studies to conduct the evaluation;"

   The selection criteria were obvious, the worst-case results were used, i.e., the tests that showed the highest leakage. It is true though, that in selecting the leakage rates to be used in the equation to calculate APFs, the authors did not always choose the worst-case situation. My quick calculations indicate that, had they done so, certain APFs could have been close enough to 1 to be of no use.

4. "the formulas and calculations used in the evaluations;'

   The simple additive model and the "improved" model seem to be fairly reasonable ways of estimating an overall respirator protection factor. My problem arises with the way in which the authors used the data from the four research studies as input into the formula. As I mentioned, they tightened up (on the "conservative" side) at each step and almost backed themselves into a corner where they would have had to eliminate a type of respirator. The industrial hygienist in me has a problem with the attitude that, in using data, we have to strive for a zero risk. If this were required of all risk assessments, particularly for common hazards, then we would all be walking to and from work. I am particularly unhappy with their use of the leakage for the most penetrating particle size. Since the diameter of most penetrating particles through the filter generally coincides with the diameter of least overall deposition in the body, the choice is unnecessarily conservative. This is particularly important since most aerosols in the workplace are much larger. This drives the user into using a HEPA filter when a DM or DFM would be a practical means of reducing the risk to the worker. It is curious that the authors criticize the ANSI Z88.2-1992 standard for doing just that. In the last paragraph of Section 16 of the draft, it is easy for me to substitute "NIOSH" for "ANSI" and be comfortable with how the paragraph reads.

5. "the conclusions of the evaluations."

Obviously, I do not concur with the conclusions since I believe that NIOSH has not been completely objective in their evaluation. ISEA makes a good point when it criticizes the use of upper or lower confidence limits or one-sided tolerance limits depending on whether they support the NIOSH thesis. Also, NIOSH chose to ignore the ISEA studies. If indeed this is the case, they immediately lost objectivity as well as my support. I am not aware of which studies ISEA is referring to, but they should at least have been considered if they were offered.

In conclusion, I would like to recommend that NIOSH rethink their stand on this issue. It seems prudent for NIOSH to get a representative cross-section of the respirator community together to discuss this subject and provide NIOSH with a more balanced view. I would feel better about supporting an approach that was based on more interaction among all concerned parties than one which comes from a single agency. Also, I would prefer to be involved in some discussions with all concerned parties before making up my mind on the best approach. With only the NIOSH and ISEA input available, I would have to vote for not changing any APFs.

Sincerely,

Bruce D. Reinoth
Section Leader
Research and Development Section
Industrial Hygiene and Safety Group

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HS-5 Group Files (K486)
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