LETTERS TO THE EDITOR

Issues for Variability

This letter is to comment on what I find a flawed logic recently offered by Myers and Zhuang[1] in support of the current assigned protection factor (APF) of 10 for air-purifying half-mask respirators. In brief, the authors looked at 205 pairs of inside- and outside-the-respirator contaminant concentration values (denoted C_I and C_O, respectively) for which C_O was between 1×PEL and 10×PEL, and found that 1/205 C_I values (or 0.5%) exceeded the PEL. (Note: According to Figure 3, Reference 1, it appears that 207 C_O values fell within the 1×PEL to 10×PEL interval.) From these data, they concluded that the probability of overexposure $Pr[C_I > PEL]$ while wearing an air-purifying half-mask respirator was only 0.5%, (or perhaps 3% if an estimated negative bias in measuring the C_I value was corrected), and they deemed the current APF of 10 to be appropriate.

I believe there are three errors in the preceding logic. First, Myers and Zhuang ignored the possible distributions of C_O values that might be encountered by different respirator wearers, and implicitly assumed without justification that all wearers would be subject to the same C_O distribution as in their data set. In the latter, it appears that more than 80% of the 205 C_O values were < 5×PEL. However, if more than 80% had been > 5×PEL, it is likely that more than 0.5% of the C_I values would have exceeded the PEL.

To illustrate, among the 207 workplace protection factor (WPF) values in Figure 3, Reference 1, for which C_O was between 1×PEL and 10×PEL, 16/207 WPFs or 7.7% were less than 10. Now, if a respirator wearer experiences 7.7% of WPFs less than 10, and always wears the respirator when C_O = 10×PEL, then 7.7% of the wearer's C_I values will exceed the PEL. The latter result can be expressed in another way. If on a given wearing C_O = 10×PEL, there is a 7.7% chance that C_I > PEL. I will say more about the C_I distribution at the close of my letter.

The second error is that Myers and Zhuang ignored the effect of between-wearer variability in WPF values, which signifies that different wearers experience different average levels of protection. One result of between-wearer variability is that given the same C_O distribution for all wearers, $Pr[C_I > PEL]$ varies between wearers. As described in two papers previously published in the *AIHAJ*,[2,3] the set of WPFs aggregated across all wearers in a population can have a 5th percentile equal to 10, yet a substantial proportion of wearers in this same population can be inadequately protected even though C_O never exceeds 10×PEL. It is puzzling that Myers and Zhuang, along with most other respirator researchers, ignore the issue of between-wearer variability in analyzing WPF data and setting APF values.[4–8] I am encouraged that OSHA policy makers appear intent on accounting for it.[9]

Aggregation of Data Points

The third error involves the simple aggregation of data points across studies, as done in Figure 3, Reference 1. There are two aspects to this error—one is statistical and one is physical in nature. The statistical aspect is that simple aggregation permits a study that contributes a disproportionate number of data points to have a disproportionate effect on overall parameter estimates. For example, the Zhuang and Myers study[10] on respirators worn against a paint spray aerosol contributed 36 WPF values to Figure 3, while the Gaboury et al. study[11] on respirators worn against a B(a)P aerosol contributed 18 WPF values. In the paint spray study, the geometric mean (GM) of the aggregated WPF values was approximately 4000, while in the B(a)P study it was 47. If one were considering just these two studies, the estimate of a median WPF value in the larger wearer population should be some type of person-weighted average of these two GM values. Using the GM of the 54 WPFs aggregated from both studies would likely impart a positive bias to the population median estimate.

The physical aspect of the aggregation error is that WPF values measured against large contaminant particles are not comparable to WPFs measured against small contaminant particles or gas-phase contaminants. The reason involves the differential loss of contaminant mass in the face-seal perimeter leak paths based on particle size. That is, most particles with a large aerodynamic diameter d_a, say, $d_a > 10$ µm, deposit in the leak paths, while gas-phase molecules and particles with small aerodynamic diameters, say, $d_a < 1$ µm, efficiently penetrate the leak paths.[12] Loss of contaminant mass in leak paths decreases the observed C_I value and increases the WPF, but the higher WPF does not signify a lower fraction of leakage air. The net result is that basing the APF for half-mask respirators on studies involving large contaminant particles leads to overstating the protection afforded against small particles and gases/vapors. Note that in the B(a)P WPF study,[11] 86% of the B(a)P mass was in particles with $d_a \leq 3.5$ µm, and the GM WPF value was 47. The aerosol size distribution in the paint spray WPF study[10] was not characterized, but most mass was likely in particles with $d_a > 10$ µm; the GM WPF was approximately 4000.

Although there is ample laboratory evidence for differential loss of particle mass in leak paths based on particle size,[12-14] I note that Myers et al.[15] have argued that such differential loss does not occur when respirators are worn in the workplace. Their cited evidence is that particles with $d_a > 10$ µm were observed on in-facepiece filter samples in a WPF study conducted in foundries. However, observing such particles does not speak to a difference in the particle size distributions inside and outside the respirator facepiece, and the authors presented no data permitting a comparison. Therefore, the in-facepiece aerosol may have been substantially depleted of large particles relevant to the ambient aerosol, even though large particles were found inside the facepiece. In fact, such differential loss of particle mass in leak paths likely contributes to an observation made in several WPF studies that C_O and WPF values are positively correlated. It has been suggested that higher particle C_O values are associated with larger mass median aerodynamic diameters, and a concomitant decrease in the fraction of particle mass that can penetrate the leak paths.[16,17]

Although I find fault with the logic offered by Myers and Zhuang, I do agree with their view that an assessment of respirator efficacy ideally should be based on comparing a wearer's C_I distribution with the pertinent PEL. If a given wearer's C_O and WPF distributions were both lognormal (as is typically assumed) with known geometric mean and geometric standard deviation (GSD) values, and if C_O and WPF were independent (as is likely true for gas-phase contaminants), the C_I distribution would also be lognormal with:

$$GM[C_I] = GM[C_O]/GM[WPF]GSD[C_I]$$

$$= \exp\left(\sqrt{\ln^2 GSD[C_O] + \ln^2 GSD[WPF]}\right)$$

In this case, $Pr[C_I > PEL]$ could be estimated as follows:

$$Pr[C_I > PEL] = 1 - \Phi\left(\frac{\ln[PEL/GM[C_I]]}{\ln GSD[C_I]}\right)$$

where $\Phi(z)$ denotes the cumulative standard normal distribution function evaluated at the argument z. A correlation between ln C_O and ln WPF can be accommodated. To assess the adequacy of respiratory protection, one would also need to consider the statistical definition of the PEL, which is not as straightforward as it seems.[18]

The practical problem with this approach, however, is that the form and parameters of a given wearer's C_O and WPF distributions will never be known *a priori*. For the reasons previously discussed, a given wearer's WPF distribution is unlikely to conform to the WPF distribution depicted in Figure 3, Reference 1, and there is no justification to assume that the wearer's C_O distribution will conform either. It has been my personal experience that most respirator selection is made on the basis of few if any C_O measurements, in which case a wearer's C_O distribution is typically undefined.

Conclusion

From the regulatory standpoint, it is not currently feasible to require an employer to measure WPF values, nor is it feasible to require an employer to make numerous C_O measurements for all respirator wearers. Further, the revised OSHA respirator standard does not mandate that any C_O measurements be made, but simply requires that the employer make "a reasonable estimate" of employee exposure.[9] Given the practical limitations of directly assessing a wearer's C_I distribution, I favor the following approach. First, the APF should be derived from WPF data analyzed to account for between-wearer variability in WPFs and for contaminant mass losses in faceseal leak paths and in the respiratory tract. Second, unless an employer adequately characterizes the wearer's C_O distribution by random measurements or by several "worst-case" measurements (or by using an appropriate mathematical exposure model), it should be assumed that the respirator is always worn at the maximum use concentration defined as APF×PEL. I cannot address the specifics of deriving the APF here, because it is a fairly complicated discussion and I fear the length of my letter has already tried the Editor's patience. The specifics are presented in report that can be obtained from OSHA.[19] Thank you for permitting me to comment.

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REFERENCES

1. **Myers, W.R., and Z. Zhuang:** Field performance measurements of half-facepiece respirators: Developing probability estimates to evaluate the adequacy of an APF of 10. *Am. Ind. Hyg. Assoc. J. 59*:796–801 (1998).
2. **Nicas, M., and R.C. Spear:** A probability model for assessing exposure among respirator wearers: Part I—Description of the model. *Am. Ind. Hyg. Assoc. J. 53*:411–418 (1992).
3. **Nicas, M., and R.C. Spear:** A probability model for assessing exposure among respirator wearers: Part II—Overexposure to chronic versus acute toxicants. *Am. Ind. Hyg. Assoc. J. 53*:419–426 (1992).
4. **National Institute for Occupational Safety and Health (NIOSH):** *Respirator Decision Logic*. NIOSH, Department of Health and Human Services, DHHS/NIOSH (pub. no. 87–108) May 1987.
5. **Johnston, A.R., W.R. Myers, C.E. Colton, J.S. Birkner, and C.E. Campbell:** Review of respirator performance testing in the workplace: issues and concerns. *Am. Ind. Hyg. Assoc. J. 53*:705–712 (1992).
6. **Howie, R.M.:** Protection factor: the need to agree on a definition. *J. Int. Soc. Respir. Prot. 12*:24–25 (1994).
7. **Nelson, T.J.:** The assigned protection factor of 10 for half-mask respirators. *Am. Ind. Hyg. Assoc. J. 56*:717–724 (1995).
8. **Nelson, T.J.:** The assigned protection factor according to ANSI. *Am. Ind. Hyg. Assoc. J. 57*:735–740 (1996).
9. **Occupational Safety and Health Administration (OSHA):** 29 CFR Parts 1910 and 1926, Respiratory Protection, Final Rule. OSHA, Department of Labor, *Federal Register Vol. 63, No. 5,* January 8, 1998.
10. **Zhuang, Z., and W.R. Myers:** Field performance measurements of half-facepiece respirators—paint spraying operations. *Am. Ind. Hyg. Assoc. J. 57*:50–57 (1996).
11. **Gaboury, A., D.H. Burd, and R.S. Friar:** Workplace protection factor evaluation of respiratory protective equipment in a primary aluminum smelter. *Appl. Occup. Environ. Hyg. 8*:19–25 (1993).
12. **Hinds, W.C., and P. Bellin:** Performance of dust respirators with facial seal leaks: II. Predictive model. *Am. Ind. Hyg. Assoc. J. 48*:842–847 (1987).
13. **Holton, P.M., D.L. Tackett, and K. Willeke:** Particle-size dependent leakage and losses of aerosols in respirators. *Am. Ind. Hyg. Assoc. J. 48*:848–854 (1987).
14. **Myers. W.R., H. Kim, and N. Kadrichu:** Effect of particle size on assessment of faceseal leakage. *J. Int. Soc. Respir. Prot. 9*:6–21 (1991).
15. **Myers, W.R., Z. Zhuang, T. Nelson, S. Sides, and D. Wilmes:** Field performance measurements of half-facepiece respirators—study protocol. *Am. Ind. Hyg. Assoc. J. 56*:765–775 (1995).
16. **Wallis, G., R. Menke, and C. Chelton:** Workplace field testing of a disposable negative pressure half-mask dust respirator (3M 8710). *Am. Ind. Hyg. Assoc. J. 54*:576–583 (1993).
17. **Wallis, G., R. Menke, and C. Chelton:** Letter to the Editor: Particle size selectivity in respirator performance. *Am. Ind. Hyg. Assoc. J. 57*:972–973 (1996).
18. **Nicas, M., B.P. Simmons, and R.C. Spear:** Environmental versus analytical variability in exposure measurements. *Am. Ind. Hyg. Assoc. J. 52*:553–557 (1991).
19. **Nicas, M.:** "The Analysis of Workplace Protection Factor Data and the Derivation of the Assigned Protection Factor." U.S. Department of Labor (no. B9F53504), September 19, 1995.

Authors' Reply

Thank you for the opportunity to respond to the letter from Dr. Nicas. We would like to acknowledge Dr. Nicas for raising the issues he has, and we appreciate his observations. While we have differences of opinion and interpretation, we sincerely appreciate the scholarly spirit in which they are offered and the opportunity to engage in a scholarly discussion about them.

As a general comment, Dr. Nicas' letter is, in the main, a discussion of one central issue: whether or not the sample of C_O and C_I used in the paper is representative of an appropriate aggregate "real-world" exposure for all half-facepiece respirators selected based on an APF of 10.

In response we would like to point out that the main point of the article was methodological. It was to illustrate an approach to assessing the APF rather than to make a definitive assessment based on the approach. As was stated in the paper, the estimate of p might well change if and when new information regarding the joint distribution of C_O and C_I becomes available. The statement in the paper that "The authors believe the current APF of 10 for half-facepiece respirators is adequate," which is the evident focus of Dr. Nicas' letter, should be read in that light. Further, it should be pointed out that shortcomings in the currently available data will affect other methods of assessing the adequacy of a given APF to the same extent that they will affect the method proposed in this paper.

The following comments deal with the specific points raised by Dr. Nicas.

First, Dr. Nicas questions the logic on which we deemed the current APF of 10 to be appropriate because he feels we ignored the possible distributions of C_O values, or, more precisely, he feels that our data may not be completely representative of the real world. We concede that any conclusions drawn from our data are necessarily subject to qualifications dependent on the representativeness of the data. In this respect our paper is no different from many other papers dealing with the same subject matter or even other industrial hygiene subject matter. Dr. Nicas concludes his argument with the illustration that "if a respirator wearer experiences 7.7% of WPFs less than 10, and always wears the respirator when C_O = 10×PEL, then 7.7% of the wearer's C_I values will exceed the PEL." Indeed, the logic in the illustration is correct but the underlying assumption is highly questionable. Its veracity is based solely on the condition that C_O = 10×PEL. Before embracing the conclusion that 7.7% of the wearer's C_I values will exceed the PEL, one must ask "What is the likelihood that any worker always wears the respirator under the exposure condition of C_O = 10×PEL?" We believe that probability is extremely low. In fact, examining the 205 data points presented in the paper for PEL ≤ C_O ≤ 10×PEL we find no values of C_O meeting the criteria of C_O = 10×PEL. Seven data points out of 205 or ≈3.4% were found in the interval 9×PEL ≤ C_O ≤ 10×PEL or, stated in the converse, ≈ 96.6% of the C_O observations were < 9×PEL. Therefore, we feel that the hypothetical use restriction of C_O = 10×PEL for a single respirator wearer is unrealistic.

Between-Wearer Variability

The second issue raised by Dr. Nicas is that "Myers and Zhuang ignored the effect of between-wearer variability in WPF values." It is hard for us to understand on what basis such a statement can be made, given that the data reported on were obtained from more than 100 different wearers in these many different studies. If Dr. Nicas meant to say the study ignores the effect of *within*-wearer variability, he is correct. The implications of ignoring within-wearer variability are discussed immediately following in conjunction with other of Dr. Nicas' statements. His statements that "One result of between-wearer variability is that given the same C_O distribution for all wearers, Pr[C_I > PEL] varies between wearers . . . yet a substantial proportion of wearers in this population can be inadequately protected even though the C_O never exceeds 10×PEL" are really about policy rather than methodology, and again the apparent issue is within-subject variability rather than between-subject variability. If standards were set to reflect within-subject variability, and to assure that no more than x% of workers should be exposed more than y% of the time, the methodology described in the paper could be adapted to do that. In that case, each worker would be described by his upper y% exposure rather than by his average exposure. So, whether the point is or is not valid, it is somewhat tangential to the paper.

Real-World Exposure

Dr. Nicas' statement that "The third error involves the simple aggregation of data points across studies" is hard to respond to adequately beyond saying that it goes into the very difficult question of what is the overall "real-world" exposure to which users of half-facepiece respirators are subjected. This is certainly an important question and one that needs to be addressed, but there are at this point in time, no definitive data to do so. We disagree with Dr. Nicas' theory for the physical aspects of the aggregation error, i.e., particle size and face seal leakage. It has been shown by several laboratory studies, including our own, that face seal leaks demonstrate differential particle loss based on particle size.[1-3] However, in all these studies the face seal leaks were created with capillary tubes, holes, wire under the face seal, etc., that resulted in leaks that had fixed and stable size, geometry, and location. The results suggest that the magnitude of differential particle loss is also a function of the leak size (e.g., diameter of capillary) and leak length (e.g., length of the capillary used to model the leak). In real-world situations the size, geometry, and location(s) of face seal leaks are neither fixed nor stable. In some instances, visual as well as microscopic evidence indicates that the overall seal of the respirator is very good but punctuated by moments of catastrophic failure during which even very large particles enter through the face seal. We are therefore led to the conclusion that "yes," differential particle loss will occur, but the variable nature of face seal leak size, geometry, and location experienced in real-life use of respirators overwhelms its potential significance in defining differences in respirator performance. Contrary to Dr. Nicas' assertion that particle size is the determining factor for the higher WPFs in the paint overspray study, we believe there are other more highly probable explanations. First of all, the half masks were equipped with HEPA filters. Nelson has analyzed half-facepiece WPF data and found that use of HEPA filters resulted in higher average WPFs than [use] with other categories of particulate filters.[4]

Second, and probably most important, the presence of solvent vapor provided the workers and the authors, who were also wearing respirators, with constant feedback on the fit of their respirators. As soon as any face seal leak developed, the smell of solvent alerted the wearer and corrective action could be taken to reseal the respirator.

Finally, Dr. Nicas remarks that "From a regulatory standpoint, it is not currently feasible to require an employer to measure WPF values, nor is it feasible to require an employer to make numerous C_O measurements for all respirator wearers." We would like to point out that the proposed method and discussion contained in the article has nothing to do with the regulation of empoyers. It focuses on addressing the question of whether half-facepiece respirators selected for use under the rubric of an APF of 10 provide adequate protection from overexposure. It may be true that measuring in-facepiece concentration values (C_I) is not currently feasible; however, measurement of C_O is equivalent to collecting a personal sample. Therefore it is feasible and is already required when assessing airborne exposures.

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REFERENCES

1. **Myers, W.R., H. Kim, and N. Kadrichu:** Effect of particle size on assessment of faceseal leakage. *J. Int. Soc. Respir. Prot. 9*:6–21 (1991).
2. **Hinds, W.C.:** "Respirator Performance Model for Particulates." Los Angeles: UCLA School of Public Health, Dept. of Environmental Health Sciences, Center for Occupational and Environmental Health (grant no. R01-OH-01595), 1992.
3. **Holton, P.M., and K. Willeke:** The effect of aerosol size distribution and measurement method on respirator fit. *Am. Ind. Hyg. Assoc. J. 48*:855–860 (1987).
4. **Nelson, T.J.:** The assigned protection factor of 10 for half-mask respirators. *Am. Ind. Hyg. Assoc. J. 56*:717–724 (1995).

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