Miller, Diane M. (CDC/NIOSH/EID)

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Attachments: NicasTILComments.pdf

Please find attached my comments on the NIOSH proposed total inward leakage tests for air-purifying halfmask respirators.

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Comments on the NIOSH Total Inward Leakage Proposal

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I highly commend NIOSH for promulgating regulations for total inward leakage tests as part of the testing and certification process for filtering-facepiece respirators. Based on my understanding of the current proposal, I offer comments in three areas.

The Number of Fit Tests Per Panel Member: My understanding is that each panel member would be allowed up to three tries to pass a QNFT with the candidate respirator, such that just one pass outcome out of the three trials would qualify as an overall "pass" result. This makes little sense and simply promotes the acceptance of poorly fitting respirators. The three trials would make sense if three different sizes of the same model respirator were being tested such that a wearer had the opportunity to don the size that fit the best, but I do not think that is the circumstance here. The only way in which performing three tests make sense is if the three fit factors (FFs) were used to estimate the 5^{th} percentile FF for the wearer, and if NIOSH were to specify a pass criterion 5^{th} percentile FF such that the wearer had to achieve a 5^{th} percentile FF equal to or greater than that pass criterion value. Past testing indicates that replicate FFs on the same wearer with the same respirator are lognormally distributed, so obtaining three FFs would permit estimates (albeit uncertain) of the GM and GSD for the wearer's FF distribution, and in turn, for the wearer's 5^{th} percentile FF. Unless such a statistical approach were adopted, or unless different sizes of the same model were being tested, there should be just one fit test per panel member.

The Panel Pass Criterion: I found the discussion of the pass percents to be ambiguous and confusing, and I suggest a clear and simple statement. First, NIOSH should articulate a specific goal for the population proportion that achieves an acceptable fit with a respirator, and should articulate the desired confidence level in its decision that a given respirator provides an acceptable fit to that desired proportion. I suggest the target proportion be 80% and the confidence level be 90%. I also suggest that if the respirator comes in different sizes, each panel member be allowed one trial with each size.

Given the desired 90% confidence that the respirator fits no less than 80% of the population, at least 32 of the 35 panel members need to pass the fit test. To be strict, the 32/35 cutpoint would provide approximately 90% confidence that no fewer than 82% of the population achieves an acceptable fit. The 32/25 cutpoint is based on the binomial probability distribution, which is the same probability model relied upon by NIOSH. The table on page 2 shows that for a population proportion $P \leq 0.81$ and a panel size $n = 35$, the percent chance of the respirator failing the panel test (that is, fewer 32 panel members pass) is at least 90%. For each P, the listed percent was computed by the equation:

$$\text{Percent Chance} \geq 32 \text{ out of } 35 \;=\; 100\% \times \sum_{k=32}^{35} \binom{35}{k} P^k (1-P)^{35-k}$$

As seen in the table, the drawback of my proposal is that respirators that truly fit 80% to 90% of the population have less than an even chance of passing the panel test, and one does not reach a 90% chance of passing the panel test until P = 0.95. The only way to correct that situation is to increase the panel size. For example, a panel size n = 100 and a pass criterion of at least 85 out of 100 would provide >50% chance that a population with P ≥ 0.85 satisfied the pass criterion, and would provide >90% chance that a population with P ≥ 0.89 satisfied the pass criterion.

True P	Percent chance that ≥ 32 out of 35 panel members pass the fit test
0.7500	1.3611
0.7600	1.8696
0.7700	2.5440
0.7800	3.4292
0.7900	4.5782
0.8000	6.0524
0.8100	7.9212
0.8200	10.2605
0.8300	13.1495
0.8400	16.6664
0.8500	20.8819
0.8600	25.8503
0.8700	31.5984
0.8800	38.1125
0.8900	45.3245
0.9000	53.0985
0.9100	61.2208
0.9200	69.3971
0.9300	77.2618
0.9400	84.4054
0.9500	90.4245
0.9600	94.9973
0.9700	97.9780
0.9800	99.4892
0.9900	99.9591
1.0	100.0000

Passing a Fit Check: NIOSH should require that a wearer be able to successfully perform a fit check on the filtering-facepiece respirator. It is essential for adequate respiratory protection that such a fit test be performed and, of course, fit checks are required by OSHA 29 CFR 1910.134 for negative-pressure air-purifying respirators.

Therefore, the NIOSH should not certify a respirator unless the manufacturer provides a reliable means for fit checking. A minimum demonstration of reliability would be to take a panel of individuals who have successfully passed the QNFT, have them redon the respirator, have them perform a fit check, and then conduct another QNFT to assess whether they achieve an adequate fit. If more than 10%, say, of the panel fails the QNFT, the fit check procedure is not reliable. I say this is a minimum demonstration because it does not adequately account for the variability in FFs fit between different donnings of the respirator. At the same time, it is better than not performing any reliability assessment of the fit check procedure.