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HIGHLIGHTS

Technical Information for Occupational Health and Safety Professionals

NIOSH cites poor fit of many current N95s, urges fit test change

The first two articles of this issue are reprinted with permission of TB Monitor, American Health Consultants, Atlanta, Georgia, in which they first appeared. 3M OH&ESD strongly disagrees with a number of the assertions made by individuals in the first article. We are in full agreement with the rebuttal points raised in the second article Performance of N95 Respirators-Another Perspective.

Quantitative tests needed to weed out poor products

Many respirators worn by health care workers evidently are constructed so poorly that they fit few people properly, say researchers at the Center [sic] for Disease Control and Prevention's National Institute of [sic] Occupational Safety and Health (NIOSH).

In two separate studies — one published in 1996[1], the other still awaiting publication — laboratory researchers in NIOSH's Respiratory Disease Studies Division found that many N95 half-mask filtering facepiece respirators perform poorly when tested on a panel of health care workers.

In a study published in 1998, a panel of 25 test subjects who were experienced in donning respirators tried on all 21 of the N95 respirator models available at that time. Three of the models failed to pass a subsequent fit test on any of the test subjects. In addition, 17 of the 21 respirator models tested had acceptable fit tests for fewer than half of the panel members.

"If you look at all 21 models, on average, only about 45% of the people successfully passed the fit test," says Chris Coffee [sic], PhD, a senior research chemist at the laboratory research branch of NIOSH's Division of Respiratory Disease Studies and lead researcher for the 1998 study.

The data from that study were originally published without naming the manufacturers. After a period of debate, NIOSH staffers made the decision to release the names of the manufacturers, which are published here for the first time. (See chart, p. 31[sic].)

A second, still-unpublished study by Coffee and others that tests the generation of N95s now on the market shows the same poor level of performance, says Coffee. "Based on what we're writing up now, the fitting characteristics [of currently available N95s] have not increased dramatically," he says. The new findings should be published sometime early this summer.

Many experts at NIOSH say they worry that the poor-fitting respirators pose a threat to health care workers. "The worker is the one who has the potential to lose here," says Paul Jensen, PhD, chief of the laboratory research branch. "There are respirators out there that truly don't fit, but they're still being sold. So instead of having superior-fitting respirators, we have respirators that rely on the employer to make sure they fit properly."

"When we look at current models, and we do the standard tests, we see very high failure rates," adds Donald Campbell, PhD, a research scientist in the same branch as Coffee. "We have to wonder: How can they sell such things?"

Campbell, Jensen, Coffee, and others interviewed for this story all say they'd like respirator manufacturers to be held more accountable for the quality of their products — perhaps by putting a fit testing component back into the certification process.

"NIOSH in general would like to pursue a fit test standard" for manufacturers, says Richard Metzler, acting director of NIOSH's newly created National Personal Protective Technology Laboratory. "Our hope is to put [a fit test] back into the proposed standard that we use in our respirator certification program."

That would have the effect of put-

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ting more responsibility for the fit onto the manufacturer, says Jensen. "We'd like to have it more balanced, so that workers are provided with a good respirator, and fit testing becomes a double-check instead of the primary means of assurance," he says.

In the meantime, Metzler, Jensen, Coffee, and others at NIOSH say it's especially important for employers to make sure their employees are adequately protected — and not just by fit-testing, but by using a quantitative fit test, not a qualitative one, they add.

Quantitative fit tests compare two measurements: the number of particles outside the respirator and the number inside. Qualitative tests, by comparison, rely solely on subjective reports of smelling or tasting a test agent introduced into a test chamber.

Data from studies by Coffee and others have shown that quantitative fit tests are much more reliable than the qualitative tests in widespread use throughout the health care industry.[2] Manufacturing industries have moved much more swiftly than the health care industry in adopting quantitative fit testing.

Coffee's research shows that qualitative fit tests are prone to produce false negatives; that is, the tests often show a poor fit for respirators that actually do fit well. Using the Bitrex test, a subjective fit test, Coffee found that in 41% of the tests, wearers flunked the test, even though they were receiving adequate protection. In addition, in 9% of cases, wearers passed the test but actually received inadequate protection.

Coffee's forthcoming publication is expected to recommend that fit testing programs in hospitals and other health care facilities switch from the qualitative to the quantitative method of fit-testing. That would have the effect of formalizing a longstanding preference at NIOSH for quantitative fit testing.

Given the widespread deficiencies of available N95 respirators, that's the right thing to do, adds Jensen. "For now, we have to make sure the employer is doing fit testing and doing it right," he explains. "So far, [research] has shown that quantitative fit tests are much more predictive of fit than quantitative ones."

Error rate compounded with re-testing

Other recently published work from the agency reinforces the importance of testing accurately and getting a good reading the first time out. In a computer simulation, Campbell and other researchers found that subjects who flunked two fit tests and were switched to a second and then a third respirator had diminishing chances of getting a good fit, because the rate of error is compounded with re-testing, says Campbell, lead researcher for that study.[3]

Until 1995, the NIOSH certification process for respirators included a fit testing component. That part of the certification process was thrown out because the test substance, a vapor called isoamylacetate [sic], did not work well with particulate respirators, which had to be modified with a different, vapor-resistant material before tests using the substance could be performed.

Plus, one NIOSH staffer adds, some inside the agency figured that "if there were crappy masks out there, people simply wouldn't buy them — or at least, they wouldn't buy a second one."

Now, the mood at NIOSH has swung back, with many experts calling for more protection for the consumer. But a change in certification standards is probably a long way off, researchers concede. One reason is simply the enormous workload facing the short-staffed agency.

In addition, a logistical hump looms in the road: the question of whether the test panel used to assess fit is still relevant. Respirator manufacturers and NIOSH experts both agree that the panel may need to be updated, because subjects are chosen on the basis of facial types prevalent in 1972, the year scientists at Los Alamos National Laboratory in New Mexico took anthropometric measurements of face types considered typical of the U.S. health care worker population at that time. Since then, the composition of the health care work force has changed. Now, for example, there are more women and more foreign-born people working in health care.

In addition, some in the respirator manufacturing industry dispute whether the six exercises used during the fit test are relevant to tasks performed by health care workers on the job.

NIOSH researchers are preparing to undertake new anthropometric measurements, but that will take time, they say. Regarding the industry's complaints about the relevance of the exercises, Coffee says he's not convinced there's a problem. "The idea is to stress the face seal," he notes. "I don't know if the movements [in real life] are any more or less stressful, since there are no data one way or the other. We need to do a simulated workplace test, and then a fit test, and compare."

While workers wait on NIOSH for more information, it probably makes sense for the health care industry to develop its own system of certification for respirators, much as the fire-fighting industry has already done, says Coffee. "You set up your own program, basically, and leave NIOSH out of it," he says. "That way, you make sure that only good-fitting respirators get that seal of approval."

The bottom line, he adds, "is to start with a respirator that fits the majority of people — say, between 85 and 90% — and then use a [quantitative] fit test to find those without a good fit."

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Performance Testing Data for 21 N95 Filtering Facepiece Respirators for 25 Persons, 1996

Respirator model	Total penetration* (95th percentile)+	Respirators passing surrogate fit test: No. passing	Respirators passing surrogate fit test: Total penetration* (95th percentile)+
3M 1860	6%	14	3%
3M 8210	7%	8	2%
MSA Affinity Pro	18%	16	1%
Air Ace N95 Elastomeric	88%	4	1%
Alpha Protect MAS695	31%	0	NA [&]
BBI RX2	11%	15	4%
Gerson 1730	10%	5	2%
Gerson 2735	6%	9	2%
MSA Affinity	18%	0	NA [&]
Moldex 2001/2002	12%	8	2%
Moldex 2300 N95	33%	3	16%
Racal Racal	41%	3	3%
Recal [*sic*] Delta	21%	8	4%
San Huei SH3810	26%	0	NA [&]
Tecnol PFR95	19%	3	3%
Tecnol PFR95-110/114	13%	9	4%
Uvex Pro-Tech N95A	50%	11	1%
Uvex Pro-Tech N95	7%	20	2%
Willson 9510	32%	3	4%
Willson 9501	61%	1	2%
Survivair 1930	24%	6	5%
All	33%	146	4%

*Total penetration is the sum of the filter penetration and face seal leakage. For example, a total penetration of 25% corresponds to an exposure equal to 1/4 of the exposure without a respirator. Total penetration is expected to be <=10% for this class of respirators.

+Ninetyfive percent of wearers are expected to have total respirator penetration less than the stated value. For this class of respirators a value of <=”10%” is expected.

& This model failed the fit test (i.e., had a first-donning face fit leakage <=[*sic*]”1%)” with all 25 persons; therefore, the 95th percentile total penetration could not be computed.

Source: Centers for Disease Control and Prevention. Laboratory Performance Evaluation of N95 Filtering Facepiece Respirators, *1996. MMWR* 47 (48): 1045-1049

Performance of N95 respirators-another perspective

By Janice Bradley, CSP

Janice Bradley is Technical Director of the International Safety Equipment Association.

The International Safety Equipment Association (ISEA) finds it necessary to respond to the article *NIOSH cites poor fit of many current N95s*, *urges fit-test change*, published in the March 2001 **TB Monitor**. ISEA is the trade association in the United States for companies that design and manufacture protective clothing and equipment used in factories, construction sites, health care facilities, and many other settings. A number of statements made by persons and agencies in the subject article are inaccurate and misleading. The comments and conclusions drawn by the NIOSH investigators are their own, based on opinions that do not represent a consensus of experts in the field.

NIOSH researchers identify two major concerns with their comments:

- "Standard tests" show that N95 filtering facepiece respirators are ineffective, and
- Bitrex™ qualitative fit testing (QLFT) does not adeuately identify poor-fitting respirators.

They propose resolving these concerns by:

- Requiring fit testing as a part of respirator certification, and
- Requiring end users to perform quantitative fit tests (QNFT) on each respirator wearer. This is in contrast to current regulations, which allow either QNFT or QLFT to be used.[1,2]

This article will explain why NIOSH's concerns are unfounded and their proposed resolutions unnecessary.

The laboratory study cited to support the claim that N95 respirators fit poorly was conducted with an unvalidated, non-standard method.[3] Preliminary work performed by other investigators indicates that the NIOSH method is too variable to produce meaningful results. No one outside of NIOSH has used this method to draw any conclusion about respirator performance. It is also important to note that the manufacturer of the PortaCount® Plus (TSI, St. Paul, MN) chose not to adopt the NIOSH method to allow N95 filtering facepiece respirators to be fit tested with its instrument. TSI developed an alternative accessory known as the N95-Companion™ for this purpose. At best, it can be said that the results of the NIOSH study are questionable.

The NIOSH investigators further interpret their study results to be an indication of poor respirator performance and poor quality. It clearly indicates neither. Fit, quality, and performance (defined as how well a respirator protects the wearer in a workplace) are separate issues. Even if the study results are accepted at face value, the only valid conclusion that can be drawn is that some of the respirators NIOSH tested fit very few or none of the test subjects.

It is NIOSH's belief that poor fit on its panel of test subjects puts workers at risk. Again, this is clearly incorrect. For more than 20 years, Occupational Safety and Health Administration (OSHA) regulations have required each user of a filtering facepiece respirator to be fit tested by their employer.[4] Workers who do not pass a fit test conducted by their employer are not to be permitted to wear the tested respirator. If the NIOSH investigators are aware of specific employers who refuse to comply with this regulation, they should notify OSHA for appropriate enforcement action.

It should also be noted that NIOSH's contention that requiring respirators to pass some sort of fit test during certification would do nothing to increase worker protection. No panel of test subjects (neither the 1972 Los Alamos panel nor the updated panel NIOSH proposes) can represent 100 percent of the working population. Individual fit tests on each wearer will still be necessary to determine if even a "good fitting" respirator fits a specific user. It can be logically argued that NIOSH's plan to include fit testing in the certification process is counter productive to the goal of reducing workers' exposure risk. Employers who are given NIOSH assurance that they are purchasing "good fitting" respirators may be less likely to conduct the fit tests OSHA requires (Why bother? NIOSH says these respirators fit.). This would increase rather than reduce risk.

The NIOSH investigators' contention that qualitative fit tests are less effective in identifying poorly fitting respirators than are quantitative tests is not supported by available data. Analysis of respirator performance in the workplace demonstrates that both QLFT and QNFT are effective in screening out poor-fitting respirators.[5] If NIOSH is aware of data that refutes this conclusion, they should publish it. In addition, the study NIOSH cites to support their belief that the Bitrex QLFT produces false negatives (which are conservative, in that workers with acceptable fit fail the test) was performed with unvalidated procedures.[6] Accepted procedures for evaluating fit tests have been in use for nearly 10 years and have recently been formalized.[7] A previously published article demonstrated that the Bitrex fit test meets the criteria for an acceptable fit test.[8] NIOSH does not explain why they did not follow the recognized procedures to determine if the original work is reproducible. One key element in evaluating the efficacy of a fit test

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requires comparison of its failure results with the failure results of a reference fit test *without disturbing the fit of the respirator.* This is necessary so the "same fit" is evaluated by both tests. Interestingly, the conclusions to the NIOSH study state, "One possible explanation for the high error (false negatives and false positives) seen in this study could be an *inherent variation in facepiece fit between different donnings*" (emphasis added). It is puzzling that NIOSH chose an experimental method that essentially compares apples to oranges if they were truly interested in assessing the performance of the Bitrex fit test.

It must be recognized that the NIOSH computer simulation discussed in the subject article is a purely theoretical exercise.[9] NIOSH believes its results indicate that the risk of assigning an individual a poor-fitting respirator compounds as successive fit tests are failed. However, the model is based on flawed assumptions that render its results meaningless. Oversimplified assumptions were used to model a complex process. For example, "fit" is defined as a single point estimate; in reality it is a distribution of values. The model assigns people who fail an initial fit test the same fit characteristics as the original population. However, because they have failed the first fit test, they should be defined as a new group with different fit characteristics than the original group. This error leads to the incorrect assumption that the new group will continue to be assigned a poorly fitting respirator at the same rate as the original group. A second flawed assumption of the NIOSH model mischaracterizes the performance of a fit test. Any fit test has an associated beta error, which is the chance that a subject will pass the fit test with respirator performance less than the desired level. The model assumes the beta error of a fit test is uniform over the entire range of fit factors below the passing value. In reality, the beta error decreases with decreasing fit factors. This means that poorer fits are more likely to be rejected than are fits close to the passing value. In other words, the assignment error rate will be much lower than the NIOSH model indicates.

In conclusion, there is no need for the health care industry to develop its own respirator certification as NIOSH suggests. Such a system would create confusion and would likely increase the cost of respirators for health care workers. Current NIOSH certification procedures assure that all filtering facepiece respirators effectively remove aerosol contaminants. If existing OSHA regulations for fit testing are followed, the probability that poor-fitting respirators will be assigned to users is low. Economic forces will eliminate respirators that fit few people from the market: employers with sound respiratory protection programs will not buy respirators that don't fit and therefore can't be used by their employees. As in any other industry, health care facilities that administer comprehensive respiratory protection programs are currently providing effective protection to their respirator wearers.

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A critical review of *respiratory protection as a function of respirator fitting characteristics and fit test accuracy*

By Thomas J. Nelson, CIH

Tom Nelson is a consultant specializing in respiratory protection.

Introduction

The respirator certification standard no longer requires a fit test as part of certification for respirators designed to remove particulate contaminants.[1] Since this change to the approval regulation, the National Institute for Occupational Safety and Health (NIOSH) has expressed concern that the lack of such a test during

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certification may reduce protection provided to respirator users. A recent NIOSH paper studied the effect of respirator fitting characteristics and fit test accuracy on subsequent workplace performance of half facepiece respirators.[2]

As noted in the previous article *Performance of N95 Respirators-Another Perspective*, NIOSH's paper describes a complex mathematical model based on oversimplified assumptions. A careful examination of the assumptions used reveals errors that make the model's results questionable. The basic premise of the article, i.e., significant public health and economic benefits will result if "good" fitting respirators are used with accurate fit tests, is not supported by the model.

Explanation of the model

The model assumes that adequate fit is the only variable that affects workplace performance. Simple assumptions regarding respirator fit and fit test performance are used to predict protection provided to a group of workers.

Respirator "fitting characteristics" are defined as the fraction of people from a group who will achieve adequate fit in the workplace over time, designated as "h". An h value of 0.8 means the respirator will provide adequate fit for 80% of potential users. For half facepiece respirators, "adequate fit" means one which will allow individuals to achieve workplace protection equal to or better than the assigned protection factor (APF), a value of 10.

Fit test performance is modeled by the alpha and beta errors. The alpha error represents the percentage of people who have an adequate fit but fail the fit test. For half facepiece respirators, adequate fit means that a fit factor of 100 is obtained. An alpha value of 0.5 means that 50% of the people who have fit factors greater than 100 will fail the fit test.

The beta error represents the percentage of people who have an inadequate fit and pass the fit test. A fit test with a beta error of 0.1 would be expected to allow 10% of the people with fit factors less than 100 to pass the fit test. A high beta error represents a more serious problem than a high alpha error, because it represents the percentage of people who could be assigned and use respirators that don't fit properly.

To illustrate how the model was presented, assume a population of 1000 people who are candidates for half facepiece respirator use. Further assume that the fit test used for these people has a beta value of 0.1 and an alpha value of 0.5. If the respirator used has an h value of 0.8, it is presumed that 800 people would have adequate respirator fit and 200 would have inadequate fit.

The beta value of 0.1 means that 20 people with fit factors less than the required fit factor of 100 would pass the fit test (0.1 x 200 with inadequate fits). The remaining 180 people with poor fits would fail the fit test. The alpha value of 0.5 means that 400 of the people who actually have adequate respirator performance would fail the fit test (0.5 x 800 with an adequate fit factor) and the remaining 400 would pass.

The model assumes that a second fit test is performed with the same respirator on those people who fail the initial fit test. The same values of alpha and beta are used. Of the 180 people with inadequate fit that failed the initial test, 162 would fail again, and 18 would pass. Of the 400 people who failed the initial test with an adequate fit, 200 would fail a second time and the remaining 200 would pass.

In this example, the model predicts that after the second round of fit testing, 600 of the 1000 people would be assigned a "good" fitting respirator. Of the remaining 400 people, 362 would still need to pass a fit test to qualify for respirator use, and 38 people would be assigned a respirator that does not fit adequately.

In the paper, the above process is repeated with two more respirators. The authors believe that this is how a respirator program may be run.

The authors used a range of h values from 0.45 to 0.95 and values of beta from 0.05 to 0.25 to study the effects of respirator fitting characteristics and fit tests on respirator performance. They concluded that if h is greater than 0.95 and the value of beta is less than 0.05, less than 1% of respirator wearers will have performance less than the assigned protection factor. Based on their analysis, they also concluded that respirator performance decreases as the value of h decreases.

The authors also used the model to predict the number of fit tests necessary to qualify a group of workers for respirator use. For example, the model predicts that a respirator with an h value of 0.95 and a fit test with an alpha value of 0.4 and a beta value of 0.05 would require 178 fit tests to pass an entire group of 100 workers.

Concerns about the model

Several oversimplifications and errors invalidate the results obtained when the model is used.

1. People who fail the initial fit test are regrouped and assigned the same fit characteristics as the original population. In other words, the same h value is used for a respirator in both the first and second fit tests. This is incorrect, because every member of the second fit test group failed the initial fit test. For this reason, their fitting characteristics differ from the original population.

2) A more serious mistake is that the model assumes the values of alpha and beta for a fit test are constant for any fit factor. In reality, the beta value decreases as a subject's fit factor decreases. Likewise, the value of alpha decreases as the fit factor increases. Fit test validation studies demonstrate that subjects with fit factors less than 90 fail

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the fit test, and people with fit factors greater than 300 pass.[3, 4] The alpha and beta values used in the mathematical model apply only to the gray area in which fit factors lie between 90 and 300.

3) The model assumes that people who pass a fit test will always achieve respirator performance at or above the respirator's APF. Conversely, it is assumed that those who have fit factors less than 100 cannot achieve protection equal to the APF. In other words, it is assumed that there is a direct correlation between fit factors and work place performance. No such correlation has been shown to exist.[3, 5]

To illustrate the effect of the beta assumption on the model's results, consider two scenarios. In the first, the value of beta remains constant at a value 0.1. In the second, it decreases as the fit factor decreases. The theoretical values of beta by fit factor range for an accurate fit test are shown in Table I.

Respirator, "A" in this example has an h value of 0.9 and respirator "B" has an h value of 0.5. If 1000 people are fit tested with each respirator, distributions of fit factors as shown in Table II could be expected. The percentage that pass a single fit test with inadequate fit is also shown.

The NIOSH model predicts that the number of people with inadequate fits increases with decreasing h values. As shown in Table II, the *percentage* of people passing with the poorer fitting respirator actually decreases.

The results of an actual workplace protection factor (WPF) study illustrate how the results of the simulation differ from reality.[6] In the WPF study, the performance of the 3M 8210 N95 filtering facepiece respirator was measured in a battery manufacturing plant. Twenty workers were required to pass a Bitrex™ fit test to participate in the study. The h value for the 3M 8210 is 0.96 according to NIOSH's paper. The paper cites alpha and beta values of 0.41 and 0.09, respectively, for the Bitrex fit test. The NIOSH model predicts that 36 fit tests would be required to fit these 20 people with a respirator. In the study, each person passed with a single trial. This strongly suggests the model is wrong in predicting how many people will pass or fail a fit test.

Table I. Value of Beta for Fit Factor Ranges

Fit Factor Range	<10	<50	<75	<100	100
Beta	0.005	0.01	0.02	0.05	0.1

Table II. Fit Factor Distributions (Number of People in Each Range)

						Percent Passing Fit Test with Fit Factor Less Than 100	
	Fit Factor Range						
Respirator	<10	<50	<75	<100	>100	B constant	B decreases
A (h=0.9)	0	10	30	60	900	10	4
B (h=0.5)	100	100	200	100	500	10	2

Conclusion

Respirator fit is only one facet of a respirator program that is needed to assure acceptable respirator performance. The current requirement to fit test each person is effective. Numerous workplace protection factor studies demonstrate that properly fitted and worn respirators provide adequate protection. It is unclear how adding fit testing to the certification process would add value for respirator users. The important requirement for each respirator user to perform a fit test on his/her face must not be devalued or in any way diminished. The NIOSH authors' thesis that respirators with poorer fitting qualities lead to poorer workplace performance is not supported by their analysis.

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Since 1995, 3M has offered two professional development courses that provide valuable information to individuals involved in respiratory protection programs. The courses are based on the technical and regulatory aspects of a sound respirator program rather than specific products. A large equipment display from a number of respirator manufacturers is used to supplement the classroom and workshop presentations. These courses emphasize the important practical aspects of a successful program, including selection principles, cartridge change schedules, and testing breathing air quality. Both courses carry CEUs, American Board of Industrial Hygiene Certification Maintenance points, and other professional development credits.

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