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PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

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JUL 24 1979

Mr. William H. Revoir, Chairman
ANSI Z88.2 Respirator Standard Subcommittee
2000 Plainfield Pike
Cranston, RI 02920

Dear Mr. Revoir:

This letter is in reply to your letter of May 18 and includes the specific objections of NIOSH regarding your draft ANSI Z88.2-1979 standard on respiratory protection as promised to Mr. Pisciotta in my May 10 letter.

I respect the fact that you and the other members of your committee labored for four and a half years on the proposed draft. The foreward of the standard states, "The purpose of this standard is to help respirator users establish, implement, and administer an effective respiratory protection program."

It is not enough that the proposed standard may be more comprehensive and strict than the respirator requirements presented in the OSHA regulations. NIOSH believes that the standard must reflect the latest scientific information, procedures, and equipment presently available that bear on an effective respiratory protection program.

Several of the NIOSH technical objections are based on NIOSH research conducted by Mr. Nelson Leidel at the Harvard School of Public Health during 1976-77, under the direction of Professor William Burgess. During the last two years Mr. Leidel has been analyzing and writing the results of this research. Harvard has not allowed him to release drafts of his thesis during this review period. At the present time his doctoral research has been reviewed and passed by two separate academic committees with expertise in industrial hygiene, statistics, engineering, and aerosol science. They feel the research justifies the conclusions of the "NIOSH research" referred to in the enclosed detailed comments by Mr. Leidel.

I regret that the enclosed reservations were not brought to your attention earlier by Mr. Robert Mahon of my staff, who was aware of the preliminary results of this research and the implications as early as October 1977.

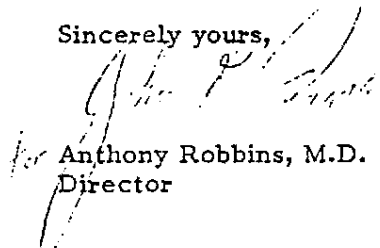
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Page-2 - Mr. William H. Revoir, Chairman

In May 1978, Mr. Leidel discussed his research findings with several members of your committee, including Mr. Bevis and Mr. Hyatt. The important point is that these research results have been independently reviewed and raise serious concerns regarding the effectiveness of respiratory protection programs as recommended in your proposed standard. They should not be ignored simply because they have not been generally available until now. I am sure that you and the members of your committee want nothing less than having your standard reflect the latest available scientific research, thus insuring effective respiratory protection programs.

NIOSH cannot support the draft ANSI standard in its present form and feels the reservations raised by Mr. Leidel must be addressed.

Sincerely yours,


for Anthony Robbins, M.D.
Director

Enclosures

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NIOSH RESERVATIONS REGARDING THE DRAFT ANSI Z88.2-1979 STANDARD
PRACTICES FOR RESPIRATORY PROTECTION (April 1979)

Nelson A. Leidel, Chief

Technical Evaluation and Review Branch

4 June 1979

Section

Comments

6.11 NIOSH will not support the use of qualitative fit tests to assign protection factors of 10 for halfmask negative pressure devices and 100 for fullface negative pressure devices. This decision is based on the results of NIOSH research demonstrating that currently recommended qualitative fit tests are not reliable procedures for screening users for inadequate fit. The parameter used for evaluating the effectiveness of the qualitative fit tests in respiratory protection programs was the accepted employee risk (AER). The AER represents direct health consequence to the employee. It is the proportion of employees in the plant that have passed the screening test, but do not have the desired protection factor.

NIOSH research indicates that, where a PF of 10 is desired, the AER can range from 0.4% to over 4% (depending on the qualitative test used) for low performance air-purifying

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halfmasks (such as the Norton 7500). The AER can range from 9% to 28% (PF = 100) for fullface air-purifying masks (such as the low performance Scott 9000). Where a PF of 50 is desired for fullface masks, the AER can range from 5% to 19%. For fullface SCBA (demand mode) units the AER can range from 7% to 17% (PF = 100) and 2% to 7% (PF = 50) for low performance devices such as the Survivair A. The current qualitative fit tests are concluded to be unreliable and potentially dangerous for use with fullface negative pressure devices where protection factors of 50 or 100 are desired.

Additionally, it should be noted that qualitative fit tests create excessive expenses in respiratory protection programs because these tests incorrectly reject a very high proportion of adequate fits. The proportion of adequate fits rejected (PAFR) by the qualitative tests for air-purifying halfmask respirators ranged from 89% to almost 99% (PF = 10). For air-purifying fullface masks the PAFR can range from about 60% to 91% (PF = 50) or 36% to 84% (PF = 100). For SCBA (demand mode) devices the PAFR can range from about 81% to 97% (PF = 50) or 64% to 95% (PF = 100).

NIOSH recommends that quantitative fit test equipment (dioctyl phthalate, sodium chloride, or equivalent) shall be used to assure respirator wearers of an adequate fit.

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6.11 NIOSH will not accept the proposed wording that assigns an individual wearer a protection factor determined from the lowest PF in a series of three quantitative fit tests. This recommendation is potentially dangerous for workers that have to wear respirators. For data from a normal or lognormal distribution, on the average about 20% of the daily average protection factors will be less than the lowest of three, with 5% to 10% being substantially lower. One-sided upper tolerance limits (UTL) should be calculated for quantitative fit test results, where each test has been performed on a different day, to determine if each wearer can achieve adequate protection on future days. This technique is explained in the enclosed "Appendix C. Note that a UTL can be calculated for as few as three quantitative fit tests, so NIOSH recommends that at least three tests be performed on different days. If the variability of the three results is low enough, initial testing may be stopped. However, if the UTL from three tests exceeds the desired protection factor used in the program, additional tests are indicated.

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Table 4
and
Table 5

No guidance is given regarding the limitations and protection factors for "single-use" or "disposable" dust respirators. Several million of these respirators are sold each month in the United States and the ANSI standard must address this class of respirators. In a series of letters written to Mr. Darryl Douglas over the period 7 October 1977 to 6 February 1978, I concluded:

- (1) It is not possible to state that all NIOSH-certified single-use dust respirators will provide at least a PF of 5 for at least 95% of the potential wearers for all dusts that the respirators are certified for and
- (2) We must be concerned about the quality of protection that single-use respirators provide employees as part of respiratory protection programs.

6.3 and
Table 4

No guidance is given the user regarding what are "sufficient warning properties." This is a critical point since the 30 CFR 11 NIOSH/MSHA approvals for air-purifying (organic vapor) devices prohibit use against organic vapors with poor warning properties. Specifically, 30 CFR 11.90(b) (note 4) covers gas masks (canister respirators) and 30 CFR 11.150 (note 7) covers chemical cartridge respirators. The limitations on the use of NIOSH-approved organic vapor cartridges or canisters must be emphasized in the standard.

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6.7 and 6.9 No guidance is given to the user regarding the possibility of very short cartridge or canister life for certain vapors and gases, especially organic vapors. There has been a wealth of literature on this subject published in the last decade, including the Gary Nelson articles and NIOSH technical publications.

A7.2 and A7.3 Warning must be given wearers that the negative pressure and positive pressure qualitative fit tests are incapable of giving the wearer positive assurance of proper protection when using negative pressure devices. This is very important, since these tests are generally recommended by manufacturers and following these recommendations is required by OSHA regulation 29 CFR 1910.134(e)(5)(i). NIOSH research indicates that for halfmasks the negative pressure test AER can range from 0.6% to 4.2% (PF = 10) depending on the make of mask. For the positive pressure test the AER can range from 0.2% to 2.7% (PF = 10). For air-purifying fullface masks, the AER can range from about 5% to 19% with the negative pressure test and 3% to 13% with the positive pressure test (PF = 50). At a PF = 100, for fullface masks the AER can range from 9% to 28%.

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A6.1

The "exercises" suggested for quantitative fit testing of facepiece respirators are misleading in that a wearer may believe that a mask's ability to provide protection has been adequately stressed. NIOSH research indicates that second, third, and fourth "exercises" (2), (3), and (4), on the average, do not significantly affect protection factors obtained using normal breathing only. The use of these "exercises" is time-consuming and provide no additional information of substantial value.

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APPENDIX C

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Calculation of Upper One-Sided Tolerance Limits for Lognormally Distributed Leakage Values

The statistical concept of tolerance limits involves the calculation of one or two values for which one can be confident (at a preselected confidence coefficient) that some proportion or percentage of the parent population is bounded. The calculation of two-sided tolerance limits create a tolerance interval. However, for respirator leakage measurements, one is generally interested in estimating a leakage value that is an upper bound for some high proportion of the parent population of leakage values. That is, one would like to calculate some upper leakage value that exceeds 95% of all other leakage values. Additionally one would like to have a high statistical confidence (such as 95%) concerning this estimate of the upper leakage value. The one-sided upper tolerance limit is the appropriate value to calculate.

Tolerance limit calculations for normally distributed populations have been discussed by Crow et al. (63), Bowker and Lieberman (64), Miller and Freund (65), and Natrella (66). However, the calculations of this study were performed using the assumption that a given series of respirator leakage values were randomly sampled from a lognormally distributed parent population of leakage measurements. Thus all leakage values must first be converted to logarithmic values before the $\log_{10}$ (upper tolerance limit) is calculated and the antilog_{10} must be taken to obtain the upper tolerance limit in percent leakage. For a random sample of lognormally distributed (and unbounded) leakage measurements the estimate for the upper limiting leakage for 95% of the parent population is calculated as follows:

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Table 20 - Example leakage measurements obtained for an employee
in a respiratory protection program.

Day of month	Leakage (%)	$\log_{10}(\% \text{leakage})$
1	0.80	-0.097
3	1.00	0.000
8	2.50	0.398
16	1.25	0.097
25	1.43	0.155

Calculate the arithmetic average and standard deviation of the five $\log_{10}(\% \text{leakage})$ values. These are $\bar{x}_1 = 0.111$ and $s_1 = 0.187$. The geometric standard deviation for the five values is 1.54. The upper tolerance limit (UTL) is calculated using the factor $K = 4.202$ so that, given the five random measurements, the probability is 0.95 that at least 95% of the parent distribution will be less than the UTL. Then the $UTL(.95, .95)$ is given by

$$\begin{aligned}
 UTL(.95, .95) &= \text{antilog}_{10} \quad 0.111 + (4.202)(0.187) \\
 &= \text{antilog}_{10}(0.897) \\
 &= 7.9\% \text{ leakage}
 \end{aligned}$$

Generally an employer would choose 10% leakage as the maximum allowable leakage for a halfmask respiratory protection program. For wearer in this example, the employer can state with 95% confidence that 95% of fits will be less than about 8% leakage. Since this UTL on leakage is less than the 10% respirator program value, the user can wear the halfmask for health protection and be assured that the desired protection can be achieved if the other guidelines of a proper respiratory protection program are adhered to.

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It is important to realize that small discrepancies in the tail of a statistical model such as the lognormal distribution should not substantially affect the conclusions and tolerance limit estimates made for the "inner body" of the distribution. One should look at where the one-sided tolerance limit lines intersect the maximum allowable leakage (screening value) chosen for the respirator program. Typically, this value would be 10% leakage ($PF = 10$) for halfmask air-purifying respirators and 2% leakage ($PF = 50$) for fullface air-purifying masks.

In a respiratory protection program, a user might be tested for respirator faceseal leakage while wearing the same model respirator on several different days. Under the assumption that the observed leakage measurements are lognormally distributed, a one-sided upper tolerance limit on multiday leakages for that wearer-mask combination can be calculated with as few as three measurements. If the assumption of lognormality for the leakage values is doubted, the values can be plotted on lognormal probability paper as discussed in Leidel and Busch (46). However, the lognormal assumption tends toward conservatism in favor of employee health protection, if in fact, the actual distribution might be closer to normal. It should be noted that tolerance limits estimated from as few as three values are typically very large and may exceed 100% leakage. This is not necessarily due to a flaw in the model, but a reflection of the fact that tolerance limit estimates from small sample sizes (less than about ten measurements) are very large due to the very large uncertainty involved in making any statistical inferences from small samples.

For example, assume that an employee has been quantitatively fit tested while wearing a halfmask respirator (fitted with a high efficiency filter) on five different days out of a month. The leakage measurements have been performed with PDOP equipment and the percent leakage values recorded as shown in Table 20.

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$$UTL(.95, .95) = \text{antilog}_{10}(\bar{x}_1 + Ks_1)$$

where $UTL(.95, .95)$ = the approximate leakage value that exceeds 95% of the parent population of leakage values (with 95% confidence probability) and

$\bar{x}_1$ = arithmetic average of the $n \log_{10}$ (leakages)

s_1 = standard deviation of the $n \log_{10}$ (leakages)

K = tolerance coefficient obtained from tables
in references (59-62)

Remember that the preceding calculates a one-sided upper tolerance limit for an unbounded lognormal distribution. In the real world, the leakage of any respirator is absolutely bounded at 100% leakage, but from a practical standpoint, the bound is usually in the range 50% to 80% leakage. Thus, the calculation of a single tolerance limit for respirator leakage data may be misleading and even alarming since values exceeding 100% can be obtained. However, this difficulty can be reduced by calculating several different upper tolerance limits for differing proportions of the parent population, plotting them on a lognormal probability graph of the sample data, and joining them to form an upper tolerance limit line. The K -values for calculating tolerance limits are typically given for 75%, 90%, and 95% of the parent population. One then compares the calculated upper tolerance line to the real world bounds to estimate the possible amount of discrepancy. The difference between the calculated upper tolerance limits and "realistic" limits that must intercept the real world bounds is substantial only for data distributions that have relatively steep slopes on the lognormal probability plots (indicating a high amount of variability in the leakage values).

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OSHA STAFF PAPER ON
RESPIRATOR PROTECTION FACTORS

First, we should define what protection factors are. A protection factor merely indicates numerically how much protection a respirator provides. Protection factor is the ratio of the concentration of contaminants outside of the respirator to the concentration of contaminants inside the respirator.

$$PF = \frac{\text{concentration outside respirator}}{\text{concentration inside respirator}}$$

In other words, if the concentration of the contaminant outside the respirator was 500 ppm, and the concentration of the contaminant inside the respirator was 10ppm; then, the protection factor for that particular respirator is $PF = \frac{500}{10}$ or 50.

The protection factor is a dimensionless number. It merely gives a numerical comparison of the amount of leakage between different respirators.

The determination of a protection factor requires quantitative tests of the respirator when worn in a test atmosphere during exercise which simulates motions made by workers.

The two test methods of respirator fitting are: the qualitative method and the quantitative method. Qualitative tests of respirator fit includes: (1) negative pressure test - this is done by closing-off the inlet to cannister, filter, or by squeezing the air line hose so that it does not pass air; then inhaling so that the facepiece collapses. After holding your breath for about 10 seconds, if the facepiece remains slightly collapsed and no inward leakage is detected, the respirator facepiece is providing a relatively good fit. (2) Isoamyl Acetate Vapor (Banana Oil) test - This test is performed by passing Isoamyl acetate around the facepiece of the wearer. If the wearer cannot detect the banana oil odor, the fit is considered satisfactory. (3) Irritant smoke - This test is similar to the Isoamyl acetate test except it uses smoke tubes which, when the ends are broken, produce irritant smoke consisting of HCL.

The advantages of qualitative tests is that they are fast, require no complicated, expensive equipment and are easily performed in the field.

The disadvantages are that they rely entirely on the wearer's subjective response, so, they are not entirely reliable. Also,

in performing the negative pressure tests, the wearer must handle the respirator after it has been positioned on the face. This of course, can affect the seal of the facepiece.

The quantitative method is the preferred method because it indicates respirator fit - numerically - and does not rely on a subjective response from the wearer. It is through this quantitative method that protection factors are determined and assigned to respirators.

The quantitative test is performed by placing the wearer in an atmosphere containing easily detectable, nontoxic gas, vapor, or aerosol. The atmosphere is usually one where aerosol NAD is generated or where DOP (Diocetyl Phthalate) is generated.

The wearer enters the test enclosure after the best qualitative fit has been obtained. The facepiece of the respirator contains a sampling tube which continuously monitors the contaminant concentration inside the facepiece. The contaminant concentration of the test enclosure is also being continuously monitored. These concentrations (both inside and outside the respirator) are fed back into a strip-chart recorder.

The wearer then performs certain exercises which simulate motions encountered by the worker performing his job. First, the wearer breathes normally - 1 minute; second, he breathes deeply - 30 seconds; third, he turns head from side to side - 1 minute; fourth, he moves head up and down - 2 minutes; and fifth, talks out loud by reading from a book, article, etc. - 1 minute. Concentration readings are, of course, registered continuously during these exercises.

The leakage of the respirator is then determined by calculating the ratio of the concentration inside the respirator facepiece to the concentration of the test enclosure. This number is our protection factor.

The greatest advantage of the quantitative method is that it indicates, numerically, how well a respirator fits. This is of great value in both respirator selection and for comparison of different respirators. The disadvantage of this method is that the equipment is expensive (\$8,000 - \$10,000) and should be operated by trained personnel.

It may be helpful to see how protection factors can be used for respirator selection in industry. If we multiply the protection

factor of a particular respirator times the threshold limit value (TLV) of a particular contaminant, this will give us the maximum concentration of the contaminant against which this particular respirator will protect. For instance, if we want to protect a worker against a contaminant with a TLV of 10ppm and we take measurements in the workplace and find that the maximum concentration of this contaminant is 500 ppm; then, we must select a respirator with a protection factor of at least 50.

$$PF \times TLV = \text{max. concentration}$$

$$PF (10\text{ppm}) = 500 \text{ ppm}$$

$$PF = \frac{500}{10} = 50$$

Just to give you a flavor of protection factors for comparison of some respirators:

A particulate removing respirator with $\frac{1}{2}$ mask - PF of 10

A particulate removing respirator with full facepiece - PF of 50

Self-contained breathing apparatus, although recent tests have yielded PF of 100 with full face piece - PF of 50

But, a self-contained breathing apparatus of the pressure demand type with full facepiece can give a PF in excess of 10,000.

One can easily see that the pressure demand is far superior as far as leakage is concerned to any other type respirator.

The whole purpose of this explanation of protection factors is to show how valuable a pressure demand breathing apparatus can be.

Persons fighting fires do not normally have the luxury of even knowing what contaminants they may be encountering - let alone what concentrations of the contaminants are present. For this reason, persons fighting fires should be provided a respirator which affords them the best protection against the unknown atmosphere they may be entering. This is why we feel that persons fighting interior structural fires, where toxic smoke and gases are present, should be provided with positive pressure self-contained breathing apparatus.

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When you need a quantitative test for mask tightness. DRAEGER.



The Mask Fit Test by National Draeger allows simple and precisely accurate measurements on any type of face mask. The testing system is based on using harmless ethylene gas as a means of evaluating breathing mask tightness. A three-reading scale amounts of ethylene gas in exhaled air. A zero reading on the gas

detector tube means a 100% tight mask. The Draeger system includes a test bag which fits tightly to the edge of all existing full face masks. test bladder used on exhalation valve of open circuit breathing systems (test bladder not used with closed circuit units). Draeger Ethylene Gas Detector Tube, Multi Gas Detector Pump, Bülford MFL



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