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16. Abstract (Limit: 200 words): This testimony concerns NIOSH's analysis of the proposed qualitative screening tests to be used in assessing fit factors of respirators. NIOSH believes that, in order to best protect workers who must rely upon respirators for health protection, a conservative approach must be used for the analysis of available data. The fundamental purpose of fit testing is to identify those prospective wearers who have unacceptable fit factors, so that the proper respirators that produce acceptable protection will be identified. For face fit testing with either the qualitative or quantitative approach, the screening level defines the acceptable and unacceptable fit factors for prospective respirator wearers. NIOSH believes that the OSHA lead standard clearly mandates that time weighted average workplace protection factors of at least 10 for half masks and 50 for full face respirators must be achieved by an employer's respiratory protection program for each individual respirator wearer. The use of the 3M Company saccharin, the Du Pont isoamyl-acetate and the irritant smoke screening tests is discussed. When trying to achieve a high probability of attaining mandated time weighted average working protection factors in the workplace, NIOSH believes that a scale down factor must be applied to fit factors obtained during quantitative fit tests.

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NIOSH Comments to DOL

SUPPLEMENTAL REPORT TO OSHA FOR DOCKET H-049A:

EVALUATION OF QUANTITATIVE AND PROPOSED QUALITATIVE SCREENING TESTS

FOR INADEQUATE FIT FACTORS OF RESPIRATOR USERS

October 1982

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

SUMMARY

In the 7 October 1981 NIOSH report to OSHA (Exhibit #37, Docket H-049A) an extensive data analysis was presented demonstrating that qualitative fit test (QLFT) protocols are intrinsically inferior to quantitative fit test (QNFT) methods. A second means of comparing proposed QLFT protocols to QNFT protocols is a statistical analysis of the error rates of the respective protocols, when they are used to screen prospective respirator wearers for unacceptable fit factors. NIOSH has previously developed and reported (Exhibit #37) statistical methodology that permits assessment of the probability (with confidence limits to allow consideration of the statistical uncertainty of an estimate) that the use of a proposed QLFT protocol will result in the assignment of an unacceptable respirator.

NIOSH has examined and analyzed the data submitted to Docket H-049A in support of the proposed qualitative screening tests. NIOSH believes many of the data sets are equivocal. However, in order to best protect workers who must rely upon respirators for health protection, a conservative, i.e., the most protective, approach must be used for analysis of available data, when differing interpretations can be drawn from the same data.

The respirator face fit test requirements of the OSHA lead standard (29 CFR 1910.1025(f)(3)(ii)) are analogous to the inspection requirements of quality assurance programs used for decades in American industry. Quality

inspection of products before they leave a production facility is used to minimize the probability of a faulty product reaching the consumer. Because industry has successfully used quality assurance programs to protect consumers, the same philosophy of quality assurance should be used to protect respirator wearers. OSHA should not require companies to provide respirators to workers without requiring fit testing that produces a very low risk that the respirators will fail to provide the protection mandated by the lead standard. The fit factor inspection procedure must yield a very low probability that respirators with "faulty fits," which would have unacceptable fit factors, would be passed by the fit test and reach the respirator wearer in the plant. This is the type of inspection that is presently provided in the OSHA requirements for QNFT in the lead standard.

The fundamental purpose of face fit testing is to identify those prospective wearers who have unacceptable fit factors, so that the proper respirator(s) that produce acceptable protection will be identified. This is to reduce the probability of overexposure so that individual workers will not be overexposed to toxic contaminants in the workplace.

For face fit testing with either QLFT or QNFT, the screening level defines the acceptable and unacceptable fit factors for prospective respirator wearers. Acceptable fit factors for individual users are those that indicate a high probability that adequate respiratory protection can be consistently achieved with the respirators for those users in the

workplace. NIOSH chose to estimate the screening error rates of the QNFT and QLFT fit factor screening tests at screening levels of 1% leakage (fit factor of 100) for halfmasks and 0.2% leakage (fit factor of 500) for fullface respirators. These values were selected for several reasons. First, NIOSH believes that the OSHA lead standard clearly mandates that time-weighted average (TWA) workplace protection factors or "working protection factors" of at least 10 for halfmasks and 50 for fullface respirators must be achieved by an employer's respiratory protection program for each individual respirator wearer. The fit factors determined by quantitative fit test methods reflect the optimal performance of only the tested respirator and cannot be considered equivalent to the TWA working protection factors that will likely be much lower.

Second, the proponents of the 3M Company saccharin, the Du Pont isoamyl acetate, and the irritant smoke screening tests assert that their qualitative fit tests have been "validated" and have the ability to efficiently screen any fit factors less than 100 (those exceeding 1% leakage). Third, NIOSH believes that a "scale-down" factor must be applied to fit factors obtained during quantitative fit tests, when trying to achieve a high probability of attaining mandated TWA working protection factors in the workplace. At present there are insufficient studies available to verify that a scale-down factor of 10, as reflected in the screening levels of 100 for halfmasks and 500 for fullface respirators, is adequate for attaining the mandated TWA working protection factors. Fourth, NIOSH believes that screening levels of 10 for halfmasks and 50 for

fullface respirators can lead to substantially inadequate respiratory protection for workers. Substantially higher fit factors must be achieved during fit testing to indicate a high probability of attaining mandated TWA working protection factors. It is insufficient health protection for workers to use screening levels of 10 for halfmasks or 50 for fullface respirators.

Lastly, even though quantitative fit methods are fundamentally and intrinsically superior to qualitative methods for screening inadequate fit factors and contributing to other aspects of a respiratory protection program, there are fundamental differences between the fit factors obtained with QNFT and the much lower TWA working protection factors that will occur in the workplace. This is because quantitative (and qualitative) fit factor screening cannot consider many causal factors that produce additional respirator leakage in the workplace due to conditions at the respirator point-of-use. Thus a screening level of 10 is inappropriate for a fit testing program, when one is attempting to obtain a high probability that a TWA working protection factor of 10 is consistently achieved for each halfmask wearer in the workplace. A fit factor of 10 for a halfmask wearer is unacceptable, since it does not indicate a high probability that a TWA working protection factor of 10 would be consistently achieved for the halfmask wearer in the workplace.

This supplemental report provides additional information to that transmitted in NIOSH reports to OSHA for Docket H-049A on 7 October (Exhibit #37) and 17 December 1981 (Exhibit #52). For the purpose of

evaluating the statistical differences in the reliability of quantitative and qualitative fit test methods, an index denoted beta is used. Part of this report presents empirical estimates of the error rate beta for quantitative fit tests used as screening tests for halfmasks and fullface respirators. Beta is the probability of judging an unacceptable fit factor (under the conditions of the fit test) as acceptable, when the fit factor at the time of testing is actually less than the selected screening level. The methodology used by NIOSH to arrive at the beta estimates is presented in detail.

The screening error rate for any given wearer population is dependent on the fit factor screening level, the QNFT screening criterion, the power function of the screening test (at leakages exceeding the screening level), and the population's leakage (fit factor) cumulative distribution function (CDF) for leakages exceeding the screening criterion. However, it appears that betas of about 0.04 or less can generally be expected for halfmask respirator fit factors screened by quantitative methods using a screening level and criterion of 1% leakage. That is, in the long run 4 or less per 100 respirator wearers with fit factors less than 100 would be passed by the quantitative methods. But error rates of 3 or less in 10,000 wearers can be achieved if desired by using a screening criterion of 0.8%. Similar betas of about 0.04 or less can generally be expected for halfmask respirator fit factors screened by quantitative fit tests conducted with the lower screening level and with a criterion of 10% leakage. But betas of 0.001 or less are easily attainable and can be expected for halfmask

respirators, if a screening criterion of 8% leakage is used to screen for fit factors exceeding 10% leakage under the conditions of the fit testing. That is, quantitative methods can assure that no more than 1 in 1000 wearers with fit factors less than 10 are passed.

For fullface respirators, betas of about 0.02 or less can generally be expected for fit factors screened by quantitative fit tests conducted with screening levels and criteria of 0.2% or 2% leakage. However, betas of 0.0003 or less are easily attainable and can be expected for fullface respirators, if a screening criterion of 1.6% leakage is used to inappropriately screen for fit factors exceeding 2% leakage under the conditions of the fit testing. The minimal reductions in the screening criteria for the quantitative fit test protocols create negligible additional costs, but provide substantially more powerful screening tests for fit factors obtained under the conditions of the testing, where only one fit test result is compared to the screening criterion.

SUMMARY CONCLUSIONS

Based on our previous comments (Exhibits #37 and #52), this more recent analysis of the available data sets submitted to OSHA Docket H-049A, and other considerations discussed in this report, NIOSH would like to emphasize:

1. A substantial number of the studies submitted to Docket H-049A we believe were inappropriately conducted, analyzed, or reported. As a result many of the data sets are unreliable indicators of how the proposed qualitative screening tests will perform in respirator programs that can be reasonably expected to be used in the lead industries. The suitable data sets may be narrowly appropriate for making inferences regarding only those screening programs conducted under the respective conditions of each study by screening personnel similar to those of the study on respirator users with characteristics similar to those of the wearers in the study. Thus, limited inferences can be made from each study submitted to OSHA.

2. The use of the Du Pont isoamyl acetate, 3M saccharin, or irritant smoke protocols could substantially increase the likelihood of assigning inadequate respirators to workers, when compared to the very low risk of the presently required quantitative method.

3. For the Du Pont isoamyl acetate, 3M saccharin, and irritant smoke protocols, there are insufficient and unreliable data available to infer there is a very low risk that workers will be erroneously passed by the screening protocols, for those respirator wearers with fit factors less than 10. This assumes the tests are administered under conditions and by personnel similar to those that can be reasonably expected in the lead industries.

4. The Du Pont isoamyl acetate, 3M saccharin, and stringent irritant smoke protocols cannot assure that respirator wearers with fit factors less than 100 will be efficiently rejected by any of the three screening tests.

5. With the 3M saccharin protocol, there can be a substantial risk to wearers with fit factors less than 100, that they will be erroneously passed by this screening test.

6. With a stringent irritant smoke protocol, e.g., a 6-exercise sequence as in the "new AISI" (American Iron and Steel Institute) protocol, there can be a very substantial risk to wearers with fit factors less than 100, that they will be erroneously passed by this screening test.