ISEA Industrial Safety Equipment Association

ISEA PANEL PRESENTATION

on

Respirator Workplace Testing and Alternatives

to the

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1. "Individual Assigned Protection Factors"
   Richard D. Grunberg, Mine Safety Appliances Co.

2. "Infeasibility of Conducting Workplace Testing"
   Donald H. Burd, Racal Health and Safety, Inc.

3. "Alternatives For Assigning Performance Levels"
   Donald P. Wilmes, 3M company

1901 N. Moore Street, Arlington, VA 22209 • Tel. (703) 525-1695 • Fax (703) 528-2148

INDIVIDUAL ASSIGNED PROTECTION FACTORS

In item number six of the Federal Register notice of this conference, NIOSH solicits information and recommendations regarding "the approaches for and benefits and limitations of assigning performance values to individual respirator models". With the current of technology to measure respirator performance and the lack of understanding of the variables that affect respirator performance, ISEA does not believe that a meaningful rating system can be developed.

RATING SYSTEMS

There is precedence for government imposed individual performance ratings for products. EPA has implemented a rating system for automobile gas mileage. There is also a rating system for wear, traction, and noise for automobile tires. EPA also rates hearing protector performance by use of a noise reduction rating.

The mileage and tire ratings are obtained from very controlled objective laboratory tests using specified equipment and very rigid test protocols. Consequently they are considered reproducible. Similar results will be obtained when the same products are retested or when the same products are tested in different laboratories.

Even though the mileage ratings are reproducible they can be very misleading. When the EPA mileage ratings were first posted on new car windows, consumers assumed that this was the mileage that they could to obtain when they drove the vehicle. The public eventually recognized, with much help from the media, that the rated mileage was only a relative number and not necessarily the mileage that they could expect to get. The EPA ratings were found to be merely a means to compare the gas mileage performance of various makes and models of automobiles. The actual mileage varies considerably due to driving habits, geography, weather, fuels, etc.

While EPA's mileage rating system relies on objective test methods, the EPA NRR does not. The test method for obtaining the NRR is highly variable because it uses human beings as test subjects. Consequently the ratings are not reproducible with data obtained from one test subject to the next, from one laboratory to the next or even for the same test subject and the same hearing protector from one test to the next. Since hearing protectors are safety devices, a large safety factor is included in the equation used to calculate the published NRR number to account for the large error possible from the highly variable test methods.

The EPA requires manufacturers to mark all hearing protector packaging with instructions for calculating the theoretical

noise level to which the wearer would be exposed while using the hearing protectors, considering the ambient noise level in the environment.

Recent studies have demonstrated that the NRR number on a product is not reliable. In fact OSHA has advised its inspectors to use one half the NRR number to calculate the expected noise level reduction because of the large error involved in the generation of the NRR number. In spite of this variability, users continue to rely on the actual NRR ratings to determine which hearing protectors should be used.

All attempts to find more objective methods to test hearing protectors have failed. Furthermore, the perceived benefit of the NRR rating, which was to enhance the state of the art in hearing protectors, has not occurred. In fact, the NRR ratings have stifled hearing protector research. For example, a dynamic hearing protector cannot be tested by the current test protocol, yet the product is extremely innovative. We believe that this type of rating system will lead some manufacturers to be innovative in finding a test lab which yields the best test results rather than developing better hearing protectors.

RATING RESPIRATORS

Measuring respirator performance is much more complicated than measuring hearing protector performance. There are many more factors that could affect total performance of a respirator.

It is interesting to note how the experts' understanding has evolved in the last couple of decades. Ten to fifteen years ago it was thought that respirator performance could be measured by a quantitative fit test. The results of those tests were termed protection factors. In fact the ANSI Z88.2 1980 standard even allowed the minimum fit factor found from three quantitative fit tests be given to the individual as his assigned protection factor.

Today it is broadly recognized that many more factors must be accounted for in addition to fit factor or total inward leakage factor in attempting to assess respirator performance. The actual performance of a respirator will depend on the type of contaminant present, the mechanism the respirator uses to eliminate the contaminant, the environment in which the respirator is used, the work being performed, and most importantly the wearer themselves.

Our ability to measure or rate the performance of a respirator is limited to just a few substances for which we have analytical methods. Most contaminants occur in the facepiece in concentrations below that which can be

measured. If we were to modify the respirators, for example going from a chemical cartridge to a particulate filter, in order to test the respirator in a contaminant for which we have identified analytical methods, we believe the results would not be the same. With a surrogate filter the weight and balance of the respirator and the resistance of the respirator would have changed, probably yielding different performance results than if the cartridge was used. Additionally, little information exists as to how the contaminant enters the respirator; therefore it would not be valid to assume the a gas or vapor would behave similar to a particulate.

Rating a respirator by its fit factor, which is the ratio of test agent outside a respirator to that inside a respirator, would also result in a meaningless system. All the research done to date has shown no correlation between the fit factor obtained from a fit test and the amount of protection the respirator will provide in the workplace. Therefore, any rating system using fit factors would be meaningless to the user in terms of the actual protection the respirator would provide in the workplace.

The results of fit testing are highly variable. A respirator with a fit factor of 15 is in reality no different than a respirator with a fit factor of 20; nor is there any difference between a respirator with a fit factor of 20,000 to one with a fit factor of 25,000. Studies have shown that because of the great variability of the quantitative fit test differences in fit factors of this magnitude are not statistically significant.

It is also quite likely that the use of such a rating system would encourage respirator users to use these ratings as assigned protection factors as was done in the 1980 ANSI standard. ISEA believes this would result in unsafe use of respirators.

We believe that the respirator fit requirements for the respirator user contained in the new 1991 ANSI Z88.2 standard is a good conservative but workable system. The concept contained in this standard of requiring a fit factor through the use of either a qualitative or a quantitative test of ten times the assigned protection factor for the respirator user is a good one.

Respirator fit, through the use of new designs and materials, has improved greatly over the past decade. This improvement came not as a result of a rating system, but because the employers are now fit testing respirators users before assignment and during periodic training. In 1980, I would estimate less than 5% of respirator users ever had any fit test performed on them. Today, I estimate more than 75% of the respirator users are fit tested periodically.

Poor fitting respirators are being rejected from the marketplace through the proper selection process by knowledgeable Industrial Hygienist, Safety Engineers, Health Physicists and other professionally trained people. If NIOSH wishes to improve respirator fit the best way would be to further encourage fit testing of all certified respirators on all the users during the selection process and during periodic retraining.

CONCLUSION

A successful respirator program relies on the worker wearing his respirator. Although respirators should meet minimum performance requirements, too much emphasis should not be placed on individual fit factors or any other single rating system. Other factors such as comfort, ease of use, ease of maintenance must be considered. The market considers these factor and will continue to do so. They will drive the progress toward respirators with better overall performance, not just higher fit factor ratings.

INFEASIBILITY OF CONDUCTING WORKPLACE TESTING

ISEA believes workplace testing of respirators would provide the best information on the actual performance of respirators if practical, reliable and reproducible tests could be conducted. Unfortunately, insufficient information exists to understand how to conduct these tests to meaning measure respirator performance. The purpose of this presentation is to explore the feasibility of performing tests in the workplace to determine workplace protection factors as part of respirator certification.

Workplace testing studies have shown properly fitted respirators adequately protect workers from workplace contaminants. They also verify the reliability and utility of laboratory performance tests of respirators to assure actual performance at the levels of exposure for which the respirators are certified. Precisely quantifying performance of individual models of respirators beyond the level for which they are approved, however, is not technically possible today.

Certification of respirators by NIOSH must be done in an equitable and impartial way and provide credible assurance that the respirator will provide the anticipated protection. Complete understanding of and confidence in the methods used in the certification is necessary to assure results. It appears that today we have more questions than answers concerning the methods to be used in workplace testing.

WORKPLACE CONTAMINANTS

Most of the workplace studies that have been conducted were done in workplaces where the contaminant of concern has been a metal. These worksites and contaminants were chosen because analytical methods with sufficiently high sensitivity exist to make them useful for this application. Even so, many data points are lost because the contaminant level inside of the respirator is below the level that even the best analytical methods can detect. When this happens one can not quantify the level of protection that a respirator is giving.

From a practical standpoint the analytical sensitivity should be at least 1000 times greater then the anticipated concentration in order to minimize the number of non-quantifiable test results. It is extremely difficult to find workplaces with sufficiently high concentrations, or continual respirator usage, especially when testing the higher performance classes of respirators. Most employers have installed engineering controls to greatly reduce the level of contaminant present.

Likewise when the tests are run in these atmospheres containing metals it is common to find vastly different protection factors for each of the different metal present. Logically this does not make sense. Particle size may be a partial answer but work needs to be done to determine whether this is an artifact of the methods used or if this is a real phenomenon. If the numbers are real which number should be used.

The analytical methods that have been identified are mainly suitable for metals. What about all the other contaminants where there are no suitable methods? In the past several investigators attempted to use gravimetric methods. Recent work indicates that the body generates much of the total mass of the particulates present inside the respirator and, therefore, this method is not suitable. In the smelter studies Warren Myers found as much chlorine inside the respirator as he did lead even though there was no chlorine outside the respirator. One must assume that the chlorine came from body generated fluids. Much more work needs to be done in this area.

For particulate contaminants much work needs to be done to determine the effect of particle size on the performance of the respirator in the workplace. Recent work indicates that collecting only respirable dust on the outside of the respirator while collecting total dust on the inside may be inappropriate because some amount of large non-respirable dust can be present inside the respirator inlet covering. This would indicate that the faceseal leakage holes are not of the filtering size. More work is needed to determine the physical nature of the particulates that are found in the facepiece.

ISEA is not aware of any reliable facepiece sampling methods suitable for sampling any of the many gases and vapors present in the workplace. To date there have been no credible studies performed to determine the workplace protection factor for gas and vapor respirators. The high humidity and insensitivity of the analytical methods so far have precluded gas and vapor contaminant workplace testing.

It is well known and reported in the literature that the human body accumulates many gases from previous exposures and eliminates them subsequently through exhalation. This makes it very difficult to determine if the contaminant present in the facepiece came from respirator leakage or came from the test subjects' exhaled breath. Test method development in this area has barely begun with very much work remaining.

TEST SITES

Finding the proper workplace test site is a very difficult task. Briefly I would like to describe several factors that must be present in order to constitute a suitable test.

1. It must contain high enough concentrations of a suitable contaminant.

2. The site must contain a large number of workers exposed to the suitable level of the contaminant.

3. The operations at the site must be such that workers remain in the contaminated area for a suitable length of time.

4. The management of the site and the workers themselves must be willing to participate in the study.

To find a worksite as described above is extremely difficult. Most employers have been installing engineering controls to reduce the airborne hazards in the workplace. The majority of workplaces have jobs where the workers are only exposed to very low levels of the contaminant for long periods of time or, alternatively, for very short times if the contaminant levels are high. Typical of the higher exposures are the maintenance-type jobs that only occur occasionally and are not scheduled, and thus are not suitable as test sites.

Another major problem that is encountered is obtaining management approval to test in their workplace. The testing imposes a considerable burden on the operation. Productivity is greatly reduced as the workers jobs are interrupted with the necessary additional training, fit testing and sampling required for the study. This is not only a burden on the employers but also the employees. Often where workers are on productivity incentive plans they will lose money. In addition, workers frequently do not want to be inconvenienced by the burden of the sampling pumps and tubing.

Suitable workplace testing sites can be found occasionally . The problem of finding suitable sites would become extremely serious if workplace testing were to become a certification requirement. There simply would not be enough available sites for testing.

OTHER PROBLEMS

Much work still needs to be done on data analysis and interpretation. Some researchers are suggesting that correction factors be added to account for lung loss, particle size, analytical error and sample probe bias. These corrections add much error in calculating respirator

performance. The corrections are usually the mean (or average) of a highly variable number.

Additional research is needed to control these variables rather than to try to correct for them. These correction factors add much variability to the measured values.

After these problems are solved, we will have to test protocols that can be used with the various contaminants and types of respirators that will be tested. A unified protocol will be necessary for reproducible results.

SUMMARY

In summary, workplace testing of respirators as part of certification is technically not possible and inadvisable as a regulatory policy. While ISEA wholeheartedly agrees with the concept of determining performance of respirators in the workplace, years of research remain before the many problems and remaining questions on how to do it are resolved. ISEA continues to support the continued research in this area.

ALTERNATIVES FOR ASSIGNING PERFORMANCE LEVELS

If we had the technical understanding to perform workplace testing in a feasible and reproducible manner, it would be the best method for assigning protection factors. Our understanding of how to perform a meaningful, reproducible workplace performance tests, however, is only in the early development stages with much research still needed. St the same time, it appears NIOSH is seeking to add more confidence that a certified a respirator exceeds its assigned protection factor.

ISEA believes that positive interim actions can be taken. First, research needs to continue on workplace testing methods to solve the many technical problems that exist. The research should continue from both a theoretical base in the laboratory and in the actual workplace. Many problems still exist with both the technical and practical aspects of the testing. For example, no one has identified any proven methods for sampling and analyzing gases and vapors inside a respirator. This clearly would be research that should be carried out in the laboratory. Testing of respirators in the workplace should continue. It appears that each time such testing is done more knowledge is gained that someday will lead to a better understanding of all the variables encountered during workplace testing.

ISEA believes that while workplace testing cannot be done today or the near foreseeable future in a feasible and reproducible manner, steps can be taken today to enhance confidence, through the certification process that certified respirators will perform adequately. I will briefly summarize those steps now.

1. Test respirators in the laboratory using upgraded bench tests.

2. Perform fit tests on a ten person anthropometric panel.

3. Conduct simulated workplace testing using the members of the above panel.

4. Conduct field evaluation of all certified respirators.

UPGRADED LAB TESTS

Upgraded laboratory tests can be used to evaluate many of the problems that are being found in the workplace. In fact NIOSH has incorporated many changes in its first proposed revision to the certification standards that we believe address many of the concerns about workplace performance of respirators. For example, the proposed regulation NIOSH has significantly upgraded the certification requirements for particulate respirators. The proposed test methods use test

aerosols considered to be the most penetrating size and thus the most difficult for a respirator to filter. The improved will assure that the respirator filter will perform in the workplace at least as well as it did in the laboratory. This provides greater assurance than exists today.

There are many other changes in the laboratory testing that can and should be done. John King will discuss many of these things in much more detail latter.

FIT TESTING

A necessary part of simulated workplace testing is qualification of the subject through the use of a quantitative fit test. The test subjects should be selected from an anthropometric panel. The panel would consist on one person in each of the boxes of the Los Alamos grid. John will discus details of this later. This will give assurance that certified respirators will fit a wide variety of people. Only subjects who have passed the test will be qualified to wear the respirator. This would be typical of real use requirements. The quantitative fit prior to simulated workplace test would be the only fit test used in certification.

ISEA believes that the only meaningful fit test is the fit test that will be performed on the actual wearer of the respirator. NIOSH should make fit testing of the respirator on the actual wearer a condition of certification. ISEA believes this is the best way to improve respirator fit. ISEA believes that a statement should be place in the NIOSH limitations that the respirator wearer be initially and periodically retested as a condition of certified respirator use.

SIMULATED WORKPLACE TEST

A practical simulated use test in the laboratory should be incorporated into the certification process. The test incorporate those factors that have been identified as being pertinent to the performance of a respirator in the workplace. Some of these variables could be workrates, wind velocities, work regimes which we have currently identified as affecting respirator performance should be included. As workplace testing research continues to identify factors affecting performance, these findings should be incorporated into the simulation tests to assure these factors are adequately addressed in respirator design and performance.

We recognize the need of researchers to correlate the results of simulated workplace testing or various laboratory testing with workplace testing. Such correlation will enhance the confidence that can be placed on non workplace testing. While direct correlation is desirable and

understandable it is apparent that researchers have not yet developed workplace tests to the point where this would be possible.

Correlations are only possible when all the variables affecting the results are known and controlled or factored in to the predictive equation. Today, our level of knowledge barely scratches the surface of all the information necessary for this understanding. Correlating one workplace study with another is not well understood let alone correlating a workplace study with any testing we would do in the laboratory.

WORKPLACE EVALUATION

NIOSH should also require a workplace evaluation of respirators in a manner similar to that done in the UK. In this evaluation respirators are put to an appropriate use for a period of time in a workplace, then brought back into the laboratory where the appropriate laboratory performance tests are then performed. Design weakness, and defects can be found after a period of actual use when performance is checked after a period of use.

For example, filter efficiencies should be checked to assure they are not degraded during use, cartridges checked to assure channeling has not occurred, exhalation valves checked to assure they do not leak. ISEA believes that this type of evaluation is not only valuable in discovering problems but is also feasible.

CONCLUSION

ISEA believes that NIOSH has already proposed many steps to add greater confidence to the respirator certification system. The additional steps that we have recommended above plus what John King will describe next will add even more confidence. With these recommended changes ISEA believes certification system in this country will far exceed that of any country in the world.

Research must continue on the methods and problems associated with workplace testing of respirators. ISEA and its members will continue support research endeavors to find answers to the many problems and questions currently shrouding our ability to perform meaningful workplace evaluations of respirators.