Role of Workplace Performance Testing in the Certification of Respirators

REPORT AND RECOMMENDATIONS (May 27, 1991) (Performed under NIOSH purchase order no. 0009142242)

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EXECUTIVE SUMMARY

This report sets forth my observations and recommendations on the role of workplace performance testing of respirators as part of the NIOSH respirator certification process. It is based on an overall evaluation of the role of workplace performance testing in the certification of respirators with primary emphasis on the technical feasibility and appropriateness from a scientific standpoint.

There is great variability in field measurement of workplace protection factors (WPFs). Some of this variability can be reduced by simulated workplace testing under controlled and reproducible conditions. Because of practical limitations on workplace testing of respirators, tests for each type of respirator would likely be conducted only in one or a very few workplaces.

The need for field performance testing is determined by the complexity of the system under consideration and the seriousness of its malfunction or inadequate performance.

In evaluating what tests are most important to me for protecting my own health in a given exposure situation, I find component testing and fit testing to be most important. The fact that a manufacturer has been able to show satisfactory performance in one workplace has no effect on my acceptance or rejection of a particular respirator.

Recommendations:

1. Because of the experimental difficulties outlined in the report, I recommend that field performance testing not be part of the certification of conventional air-purifying respirators.

2. Standardized simulated workplace testing, conducted in a laboratory, is recommended for certification of more complex types of respiratory protection systems, such as PAPRs, SCBAs and abrasive blasting helmets. There is a research need to develop standardized simulated workplace tests that reflect the range of conditions under which a particular type of respiratory protection system will be used.

3. Workplace efficacy testing can be recommended for respiratory protection systems that are significantly more complex than PAPRs, SCBAs, or abrasive blasting helmets, or systems that may exhibit unexpected behavior in certain use situations.

4) The development of a consumer information database identifying problems in field use of all types of respirators, but especially complex systems would be useful to manufacturers, regulators, users, and researchers.

5) Consideration should be given to the use of computer models to evaluate respirator performance under a wide variety of exposure conditions. Use of these models can identify those use situations for a given respirator where performance may be inadequate.

I. Introduction

The objective of this report is to set forth my views on the role of workplace testing of respirators as a condition of certification for the federally mandated NIOSH Respiratory Protective Equipment Certification Program. These views are based on many years of research involving the performance and acceptance of air-purifying respirators, publication of eight peer-reviewed papers on respirators, serving as a consultant on respiratory protection, and attendance at the NIOSH Conference on workplace performance testing held January 9-10, 1991 in Morgantown, WV. This report represents an overall evaluation of the role of workplace performance testing in the certification of respirators with primary emphasis on the technical feasibility and appropriateness from a scientific standpoint. It is not intended to be an economic or policy evaluation.

The Workplace Protection Factor (WPF) is the ratio of outside to inside concentration measured while the respirator is being worn be a worker doing their usual job. It assumes that the respirator is being used correctly and has been properly selected, fit tested, and maintained.

There are at least three ways to define the WPF. The inside concentration can be measured as a time weighted average over the period of study. This time weighted average would include periods of exhalation as well as inhalation. For aerosols, and some gases and vapors, the concentration inside the mask during exhalation is lower than during inhalation because of the retention of contaminant in the respiratory system. This lowers the average inside

concentration and raises the calculated protection factor. A worker's actual exposure reflects only the concentration in the mask during inhalation.

A more meaningful measure is the time weighted average inside concentration during inhalation only. This avoids the above mentioned problem, but has many practical problems including accurate measurement of sample volume. Closely related is the inhaled dose measurement, which represents an average concentration during inhalation that is weighted to reflect the wearer's instantaneous inhalation flow rate at any instant. For aerosols, respirator performance is poorest at the peak flow rate of the inhalation cycle, which is also the point at which the greatest dose per unit time occurs. This type of measurement, although desirable is extremely difficult to measure in the field, but it can be readily calculated for a well defined situation using a computer model, such as that described in Section II.

Probably the most meaningful measure is simply the retained dose without the respirator divided by the retained dose with the respirator. Although easy to state, this is an extremely difficult measurement to obtain. The other measures given above are approximations to this quantity that are easier to obtain. The extent of the difference between this and the other measures can be determined readily using a computer model, such as that described in Section II.

Related measures include the Effective Protection Factor (EPF) which includes the effect of nonwearing periods in the calculation of the protection factor and will generally be equal to or lower than the WPF. The Program Protection Factor (PPF), which includes all aspects of the respirator protection program and reflects the net protection provided to a population of workers. It will be equal to or lower than the EPF. The latter two measures are a matter of concern for regulators from a policy point of view, but are only indirectly related to the certification of respirators.

II. Some observations on WPF

There is great intrinsic variability in the measurement of WPFs because of the nature of the quantities being measured. This variability exists in addition to the variability of the quantity being measured, namely respirator performance, which is primarily associated with filter penetration and facial seal leakage. The source of contaminant in the workplace is variable with time and will often depend on quantities such as, production rate, process temperature and pressure. Airborne concentrations are intrinsically variable because they depend on air motion, air mixing, and worker movement in a complex and currently unknown way. There is substantial variation in the performance of aerosol filters even between filters from the same lot from the same manufacturer. Finally there is the human variability. People breathe differently, move differently, and generally behave differently while doing same job. These and other factors result in WPFs having a broad lognormal or other non-normal distribution, which complicates the statistical analysis of these data.

Much of the variability cited above for workplace testing can be reduced by simulated workplace testing under controlled and reproducible conditions. In simulated workplace testing it is relatively easy to maintain test agent concentration (and size distribution in the case of a test aerosol) constant over time and uniform throughout the test chamber. Test subject's tasks and motion can be standardized.

To conduct meaningful workplace testing of respirators, testing needs to be standardized. This provides a level playing field for all manufacturers and allows the regulator and the user to interpret the results and make comparisons. Standardized tests would prevent manufacturers from shopping around for a workplace that will provide test conditions that are favorable to their product. These needs are best met by controlled and reproducible simulated workplace testing.

The nature of workplace testing of respirators is such, that for a given respirator, tests would likely be conducted in one or a very few workplaces. This is a serious limitation because of the difficulty generalizing performance results from one or a few workplaces to the broad range of respirator applications. At some level each workplace is different. They have different sources, environmental conditions, work practices, and different chemical and physical characteristics of the airborne contaminants.

The significance of some aspects of respirator performance can be analyzed using computer models to predict the performance of air-purifying respirators. The model described by Hinds and Bellin [AIHAJ, 48, 842 (1987)] can be used to determine the effect of different particle size distributions, work rates, respirator filter types, and dead space on any of the WPFs described in Section I.

This model predicts overall respirator performance for protection against aerosols for a given respirator with a given filter. Its use requires knowing facial seal leakage as measured QNFT, knowing the approximate work rate of the wearer, and knowing the aerosol particle size distribution. It can be used only for respirator filters for which detailed performance data are available, eg. penetration as a function of particle size and flow rate. Output can include the different WPFs mentioned above as well as protection factors based on total or regional lung deposition or sampling criteria, such as those for respirable mass sampling.

Field trials are an appropriate way of uncovering unexpected problems of devices, equipment, supplies, or materials. The need for field trials increases with increasing complexity of the component under study. Thus, field trials are not needed to demonstrate the efficacy of lead bricks for radiation shielding. On the other hand complex systems, such as, software, therapeutic drugs, or smart bombs need to be extensively field tested to be sure they work according to design and have no unexpected characteristics. It is the complexity of the system and the seriousness of malfunction or inadequate performance that determines the need for field trials.

In some measure the certification process for respirators drives the development of new and improved respirators. A requirement for workplace respirator testing provides no new incentives for improving respirator performance, beyond those that now exist.

III. Development of recommendation

As stated above, workplace certification testing of respirators is appropriate for complex systems and not needed or useful for simple systems. Given my knowledge of the performance of respirators, how do I approach the problem of where to draw the line between respiratory protective devices that should have field testing and those that need not. Presented below is the thinking behind my recommendations.

At the first level, I consider what certification tests I would want to have performed on the air-purifying respirator (assigned protection factor of 10) that I am going to wear in a toxic atmosphere, for example, where the airborne lead fume concentration is ten times the TLV.

1) Filter penetration should be tested with a polydisperse aerosol whose mass median size is within a factor of two of the most penetrating size. Tests should be conducted at two or more flow rates, for example at the average inhalation flow rate for 0 and 622 kg-m/min workrate. These tests can also be conducted with monodisperse aerosols in the indicated size range. Performance criteria would be a penetration of less than 1%.

2) There would need to be some basis on which I could reliably assume that my filter and the test filter are equivalent in performance.

3) A quantitative fit test to ensure that the mask fits my face with a leakage fit factor of 100 or greater and that this fit is achieved reliability. Under these conditions the mask needs to be sufficiently comfortable for me to wear it for four hours without removal.

4) There would need to be a common sense evaluation that the mask is sufficiently sturdy and durable to function as intended.

The fact that the manufacturer has been able to show satisfactory performance in one workplace has no effect on the need for the above tests or my acceptance or rejection of a particular respirator.

To carry this line of thinking to the next level, I ask myself what kinds of tests are needed if I am going to sell, purchase, or recommend a particular air-purifying respirator for others to wear in the lead fume atmosphere.

1) Filter penetration should be tested with a polydisperse aerosol whose mass median size is within a factor of two of the most penetrating size. Tests should be

conducted at two or more flow rates, for example at the average inhalation flow rate for 0 and 622 kg-m/min workrate. These tests could also be conducted with monodisperse aerosols in the indicated size range. Performance criteria would be a penetration of less than 1%.

2) There would need to be some basis on which I could reliably assume that the filters to be used and the test filter are equivalent in performance.

3) I need to be assured that the various sizes of this model of respirator will reliability fit the worker population with a leakage fit factor of 100 or greater. Further I need to be assured that the fit testing will be conducted properly and that workers with poor fits will be identified.

4) There would need to be a common sense evaluation that the mask is sufficiently sturdy and durable to function as intended.

In this scenario, workplace performance testing is still not needed for me to recommend the use of a particular respirator. Workplace testing that could provide practical consumer information, such as problems with eye glasses, packaging problems, easily lost parts, etc., would be helpful. This is not part of the certification process and is not necessary to ensure that workers will be properly protected.

For more complicated types of respiratory protection, such as PAPRs, SCBAs, and abrasive blasting helmets, some type of overall performance evaluation is needed in addition to laboratory component testing before I would be comfortable using them myself or recommending them to workers for health protection. As described above, this type of testing can be done more accurately and reproducible by simulated workplace testing under controlled conditions.

It is likely that future respiratory protection systems will be more complicated than current designs. Designs might include, electronic regulators for SCBAs, solid state end-of-life sensors, computer controlled selection of filtration element or adsorber, or electronic service life optimization schemes. This kind of equipment is sufficiently complex that, in addition to laboratory component testing and simulated workplace testing, real workplace testing may need to be conducted in a variety of workplaces to ensure that these devices provide the requisite protection and do not display unexpected or detrimental characteristics.

IV. Recommendations

1. Because of the great experimental difficulties required to obtain accurate and meaningful field results, and the high variability and non-normality of measured performance, and the limitations of only one or a few work places tested, field performance testing is not worth the effort for conventional air-purifying respirators.

2. Standardized simulated workplace testing, conducted in a laboratory, should be used for more complex types of respiratory protection systems, such as PAPRs, SCBAs and abrasive blasting helmets. The problems noted in Section II can be better dealt with in the laboratory and such tests would be more reproducible and generalizable than field performance tests. There is a research need to develop standardized simulated workplace tests that represents the range of conditions under which a particular type of respiratory protection system will be used.

3. Workplace efficacy testing may make sense for respiratory protection systems that are more complex than those described in 2) and that may exhibit unexpected behavior in certain use situations.

4) The development of a consumer information database identifying problems in field use of all types of respirators, but especially complex systems would be useful to manufacturers, regulators, users, and researchers.

5) Consideration should be given to the use of computer models to evaluate respirator performance under a wide variety of exposure conditions. Use of these models can identify certain use situations for a given respirator where performance may be inadequate.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) The role of workplace testing of respirators as a condition of certification for the Federally mandated NIOSH Respiratory Protective Equipment Certification Program was discussed. An emphasis was placed on the technical feasibility and appropriateness from a scientific standpoint. According to the author, field performance testing is not worth the effort required because of the great experimental difficulties required to obtain accurate and meaningful field results and the high variability and nonnormality of measured performance. Standardized simulated workplace testing, conducted in a laboratory, should be used for more complex types of respiratory protective systems. Workplace efficacy testing may be appropriate for respiratory protection systems that are more complex and that may exhibit unexpected behavior in certain use situations. The development of a consumer information database identifying problems in the field use of all types of respirators, but particularly complex systems, would be useful to manufacturers, regulators, users, and researchers. Consideration should be given to the use of computer models to evaluate respirator performance under a wide variety of exposure conditions.

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