

Comments Regarding the Proposed Rule:
Revision of Tests and Requirements for Certification of
Permissibility of Respiratory Protective Devices (42 CFR Part 84)

Submitted by:
The Center for Respiratory Protection
Arthur D. Little, Inc.
Acorn Park
Cambridge, MA 02140

Introduction

The Center for Respiratory Protection (the Center) is pleased to submit its comments on the proposed rule for the revision of tests and requirements for the certification of permissibility of respiratory protective devices. The Center for Respiratory Protection is a group of 40-50 senior Arthur D. Little staff members, including certified industrial hygienists, certified safety professionals, physicians, scientists and engineers, who provide applications, testing and engineering assistance to respirator manufacturers and users.

Our comments address what we perceive to be the central issue raised by the proposed rule - the requirement that manufacturers collect workplace protection factor (WPF) and submit those data to NIOSH for use in the certification process. Within the context of respirator certification, we discuss the technical feasibility and desirability of obtaining WPF data, as well as some of the interpretative issues that would be raised. We conclude that using WPF data to bridge the gap between laboratory performance data and workplace performance data will serve neither the regulatory or the user community well, and suggest an alternative approach based on the modification of existing evaluation techniques that would not require the development of an entirely new analytical methodology.

Background

Two observations about the use of respirators in American industry will help provide a context for our comments. First, we have noted that two categories of deficiencies can have a detrimental effect on the performance

of respirators in the workplace. To the extent that the user does not receive the intended level of protection, it is attributable to either (1) a flaw in the design and construction of the device, and/or (2) a flaw in the administration of the respirator program. Design flaws include issues of construction and technology that are characteristics of the device itself. Administrative flaws include problems with the selection, fitting and maintenance of the equipment as well as the training and supervision of respirator users. Once the nature of the problem is understood, remedial measures appropriate to the situation can be designed and implemented.

Second, by an overwhelming proportion, the administrative problem is the more prevalent of the two types of problems described above. Staff members of The Center for Respiratory Protection visit hundreds of workplaces every year, and in virtually every case where respirators are misused, the reason is not the absence of effective, well-designed, well-constructed equipment. Instead, the reason is that respirator users are not trained, fit-tested or medically qualified, or that the respirator selected is inappropriate to the application.

This observation is adequately supported by the technical literature. A survey of 159 companies in the spray painting industry by Toney and Barnhart revealed that only 9 had formal training programs. Of the 55 types of respirators used in these companies, only 10 masks were specifically approved for painting operations.¹ A review of OSHA compliance activity for 1977-1982 reported

"During this period, approximately 27% of inspections in which respirator programs were reviewed resulted in a citation for a specific program deficiency. Of inspected worksites in which respirators were in use to provide protection from concentrations of air contaminants in excess of OSHA Permissible Exposure Limits, 56% had deficiencies in at least one program area. Since the violations were of the type that have been shown to lower the level of protection

¹Toney, C.R. and W.L. Barnhart, "Performance Evaluation of Respiratory Protective Equipment Used in Paint Spraying Operations," National Institute for Occupational Safety and Health, Report No. 76-177, U. S. Government Printing Office, 1976.

provided by respirators, many workers may have been exposed to inhalation hazards as the result of ineffective respirator programs."²

The presence in the marketplace of effective equipment obviously does not mitigate the need to update 30 CFR Part 11. The fact that 30 CFR Part 11 has resulted in a whole generation of excellent respiratory protective devices does not mean that recent technical and scientific advances should not be incorporated into a better certification procedure. We enthusiastically support NIOSH's goal of updating 30 CFR Part 11, and hope that the result will be enhanced protection for American workers, stimulation of technological innovation and simplification and streamlining of the certification process.

One recent technical development in particular has illustrated the need to update 30 CFR Part 11. In 1984, Myers et al. published data that showed that "quantitative fit factors as presently determined are not indicative of the workplace protection (provided by powered air-purifying respirators equipped with high efficiency filters)"³ (emphasis added). This information called into question the long-standing practice of using data generated in the laboratory as a predictor of actual workplace performance, and contributed to the urgency of the present rulemaking. In the proposed 42 CFR Part 84, this gap between laboratory performance data and that measured in the workplace is bridged by requiring the collection of WPF data. Whether that approach is the best alternative is discussed below.

²Rosenthal, F.S. and J.M. Paull, "The Quality of Respirator Programs: An Analysis from OSHA Compliance Data," Am. Ind. Hyg. Assoc. J., Vol. 46, No. 12, December, 1985, p. 709.

³Myers, W.R., et al., "Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter: Results and Discussion," Am. Ind. Hyg. Assoc. J., Vol. 45, No. 10, October, 1984, p. 681.

Discussion

Briefly, we at The Center for Respiratory Protection believe that requiring the collection of WPF data will provide information of little value to the certification process, and would not directly address the real cause of substandard respirator performance in the field. The use of WPF data as outlined in the proposed rule would involve at least two steps. First, an appropriate workplace in which measurements could be obtained would have to be identified, and second, the data collected in that use situation would have to be generalized or extrapolated to other, different, environments.

I. Site Selection

The spectrum of variables that characterize a working environment is not only difficult to define, but the effect of each of the variables on the performance of a particular respirator is poorly understood. For the sake of this discussion, however, we have outlined below four groups of considerations that will affect the level of protection afforded by a given respirator in the field:

- a. Variability in contaminant characteristics: physical form, concentrations, particle size, co-contaminants, etc.
- b. Variability in work activity: level of efforts, range of motion, rest breaks, fine motor control tasks versus gross motor control tasks, etc.
- c. Variability in environmental conditions: temperature, humidity, wind; radiant heat load, etc.
- d. Variability in worker demographics: gender, race, age, level of education, etc.

Even if a typical, or, as stated in the NPR, "strenuous", state could be defined for each of the four groups of variables, their interdependence increases the difficulty of finding a workplace in which typical or "strenuous" conditions exist for each. For example, it may be difficult to find a workplace in which strenuous work activity is performed in extreme

environmental conditions. In addition, the relationship between geographic location, environmental conditions and workforce demography may make the task of finding a test site in which those three groups of variables are appropriately defined difficult. These hypothetical problems could have very practical ramifications, as well: since workplaces in which "strenuous" work activity is required often employ predominantly men, selection of a test site based on the level of activity may preclude identification of a performance problem specific to women.

II. Extrapolation of Data

It is axiomatic that data collected in one workplace may or may not be able to be extrapolated to another workplace. Data demonstrating that a respirator works sufficiently well in Workplace X may not apply to Workplace Y, or even to Workplace X on another day.

There are several reasons for this. The most obvious is the tremendous variability that exists between and within workplaces, the effect of which on respirator performance is unclear. It is also likely, though, since the administrative deficiencies that result in reduced respiratory protection will be suppressed in a closely monitored field test, the WPF may not reflect actual working conditions in that or similar environments. It is the very workplace-specific nature of the most prevalent problems in industrial respiratory protection that will make not only extrapolation, but duplication of WPF data difficult. The most dangerous problem associated with extrapolation of field data will occur, however, if the nature of the site at which the original measurements were made prevents the identification of a design flaw (e.g., a gender-specific problem, as described above) that would have been revealed at another location.

III. An Alternative Approach.

For these reasons, we believe that it is neither possible nor desirable to devise and execute a WPF test within the context of certification. Certainly WPF data are invaluable to users looking to verify an appropriate selection of equipment, and to manufacturers looking to improve their

product. In fact, Rosenthal and Paull of The Johns Hopkins University School of Hygiene and Public Health suggest WPF testing as a respirator program evaluation tool, when they state that "... in-mask sampling over entire workshifts can provide an objective means of evaluating respirator program effectiveness."⁴ For the purposes of certification, however, we believe that the alternative approach outline below is preferable to WPF testing.

Many of the deficiencies we have described that would accompany WPF testing for certification purposes would be easily and successfully addressed if the tests were to be conducted in a laboratory setting. A test panel balanced for facial size and gender would assure the identification of design flaws specific to those characteristics. A rigorous test protocol would eliminate the problems associated with extrapolation of workplace-specific data to other environments, and would preclude having to generalize about the performance of a respirator in all workplaces based on its performance in one (or even a few) workplaces. Elimination of as many sources of variability as possible will enable NIOSH to focus on what is really the central issue: Will the respirator, when used within the context of a respiratory protection program that complies with OSHA requirements, protect workers?

We recognize that existing laboratory tests do not provide a strenuous challenge, nor do they approximate the activities that occur in American industry. However, it must be emphasized that much of the research that first identified the gap between laboratory and workplace performance measurements did not even try to approximate typical workplace activities. Myers et al., in their discussion of the methodology by which the PAPR research was conducted, state "the use of some whole body exercise in the

⁴Rosenthal, F.S. and J.M. Paull, op. cit., p. 714.

regimen was prohibited by the size and structure of the portable test booth."⁵

We respectfully suggest that the logical alternative to the quantitative fit test used by Myers et al., which does not predict workplace performance well, is a test that incorporates body movements typical of industrial work activities. Such a Benchmark Workplace Performance Test could be performed in a laboratory environment in the same manner for all respirators, and would provide a logical, defined, rigorous and equivalent challenge to the candidate device.

The Benchmark Workplace Performance Test should be viewed as analogous to the "Rainbow Passage". While we know of no instance in which workers actually repeat the words of the Rainbow Passage while on the job, nonetheless it is widely used as an exercise for speaking and mouth movement. It is valid because it is rigorous, reproducible and representative of the real mouth movement of real speaking people. Two different respirators evaluated in the same manner using the Rainbow Passage will yield results that can then be compared to determine relative performance characteristics.

Based on our experience with the development of similar tests for other government agencies, it is clearly possible to carefully define and develop an analogous test protocol for whole body movement. Though such an exercise regimen would not exactly replicate any specific workplace, it would be rigorous, reproducible and representative, and would thus provide a challenging, consistent and meaningful test. In addition to its obvious utility to certification, the data could also be used by respirator program administrators to carry out their assigned tasks.

⁵Myers, W.R., et al., "Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter - Test Protocol," Am. Ind. Hyg. Assoc. J., Vol. 45, No. 4, April, 1984, p. 239.

Conclusion

The real problem identified by Myers et al., was not that laboratory data in general could never be used to predict workplace performance. Instead, the important point made by their research is that the laboratory test that they used, which lacked "whole body exercise" did not generate data that correlated with WPF. That conclusion does not necessarily preclude the use of all laboratory tests in the certification process, but it does suggest that any test which is used provide a rigorous challenge to the candidate respirator.

In fact, the use of a laboratory-based Benchmark Workplace Performance Test in the respirator certification process addresses a number of difficult problems associated with WPF testing, such as selection of a typical, or "strenuous", workplace, extrapolation and generalization of results and the possibility of failing to identify important design flaws. In addition, a Benchmark Workplace Performance Test will provide useful comparative information to health and safety professionals charged with respirator program administration, and will thus stimulate technological innovation and development.

The most important task with which NIOSH is charged in the area of respirator certification is the provision of effective, well-designed and well-constructed pieces of equipment. Respirator program administrators can then make their selection based on the knowledge that the certification process was rigorous, reproducible and representative. A favorable performance on the Benchmark Workplace Performance Test will provide them with a presumption of performance that is not now available to them, and which could not be provided via WPF testing in a dissimilar workplace. These safety and health professionals can then turn their attention to the existing and pending OSHA requirements, satisfaction with which is the most direct way to address the ubiquitous administrative flaws in the field.

We appreciate the opportunity to present our comments on this important issue. It is clearly the goal of these hearings and the rulemaking process in general, as well as the spirit in which we submit our comments, that a

more excellent certification process result. We hope that our comments and perspective will contribute to the attainment of that goal.

Signed,

Christopher C. O'Leary

Director

The Center for Respiratory Protection

Arthur D. Little, Inc.