Assessing Powered Air Purifying and Supplied Air Respirator Performance:

An Employer's Guide to OSHA's Final Rule on Assigned Protection Factors for Respirators

An E.D. Bullard Company *White Paper*

By

John H. King
Technical Director
September 21, 2006

Preface

For well over a decade, occupational health and safety professionals have lacked authoritative governmental guidance on performance ratings (commonly referred to as a "Assigned Protection Factor" or APF) of respirators used in the workplace. OSHA published, but did not always update, a bewildering array of substance-specific standards. Across each standard one could often find an inconsistent assignment of protection factors to various classes of respirators.

Adding to the confusion for practitioners were national consensus standards developed independently of government regulations. These were based upon more recent scientific studies. Particularly for Supplied Air and Powered Air Purifying respirators, nationally recognized standards (e.g., ANSI Z88.2) promoted different (higher) Protection Factors than were published in government regulations.

During this period of "Protection Factor Limbo," manufacturers themselves began to contract for independent scientific evaluations of their respirators' performance both to add weight to the empirical evidence supporting higher Protection Factors and to provide interested customers with reassurance about the efficacy of the manufacturers' products. In some cases, these respirator manufacturers petitioned OSHA for formal recognition of the superior performance of such respirators based upon this independent research. OSHA did, in fact, write letters in some cases, acknowledging higher levels of performance as reflected in a higher Protection Factor.

OSHA finally published its long-awaited Final Rule on Assigned Protection Factors (APF) on August 24, 2006. The Final Rule takes full effect on November 22, 2006. With its new Rule, OSHA has removed nearly all the confusion and uncertainty that has characterized the past many years. However, for employers who utilize Powered Air Purifying Respirators (PAPRs) and/or Supplied Air Respirators (SARs), there remains potential for confusion. That is because OSHA has placed the burden for analyzing and interpreting the performance of specific respirator models in these two classes on the shoulders of employers.

In this White Paper, Bullard's Technical Director, John H. King, explains the background and specifics that employers need to know about respirator efficacy in order to make their own assessments in selecting specific brands and models of PAPR or SAR products. Unfortunately for both the manufacturers and the users of these classes of respirators, neither group can simply look up "THE" answer in a table in the OSHA regulation. But answers can be readily had with a bit of education on the part of the employer and solid data from the manufacturers. The objective of this White Paper is to provide the needed education.

The New Regulations Regarding Assigned Protection Factors for PAPRs and SARs

Assigned Protection Factors (APFs) provide employers with key information about a respirator's expected ability to reduce the level of hazardous particles, gases and vapors present in the work environment that reach the worker's breathing zone. Proper respirator selection is based on the respirator's APF number, the concentration of the hazard and fit testing. These are components of an OSHA-compliant respiratory protection program. As defined in the new rule, an Assigned Protection Factor is "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program [as stated in 29 CFR 1910.134]."

The new regulation may be found at Federal Register / Vol. 71, No. 164 / Thursday, August 24, 2006 / Rules and Regulations. Items 2 and 3 of the APF table (Table 1 illustrated on page 50188) deal with Powered Air Purifying Respirators (PAPRs) and Supplied Air (or Airline) Respirators (SARs). In part, the table states:

TABLE 1 (Abridged) **ASSIGNED PROTECTION FACTORS**

Type of respirator	Full facepiece	Helmet /Hood	Loose-fitting facepiece
2. PAPR	1000	[4]25/1000	25
3. SAR (continuous flow mode)	1000	[4]25/1000	25

Footnote 4 in essence states that in order to use an APF of 1000, the respirator manufacturer shall provide evidence to the employer that the respirator demonstrates performance at a level of protection equal to or greater than 1000. Thus, helmets and hoods are treated as though they were tight-fitting full facepieces if such evidence is provided by the manufacturer. Conversely, helmets and hoods are treated as though they were loose-fitting facepieces in the absence of such evidence.

OSHA intentionally did not specify a method or methods by which evidence of a respirator's performance is to be determined or measured. This is because there are no universally accepted testing protocols pertaining to measuring respirator efficacy. However, OSHA does provide guidance by stating "This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing." Referring to page 50168, OSHA apparently believes the study conducted by the Organization Resources Counselors Worldwide, published in 2001, commonly referred to as the ORC-LLNL study, could be used to make judgments as to whether the tested respirators are "worthy" of an APF rating of 1000 or not.

The ORC evaluation was a Simulated Workplace Protection Factor (SWPF) study. However, OSHA also suggests that Workplace Protection Factor (WPF) studies (page 50168) could be used as well for collecting the requisite data needed to determine if a particular respirator is worthy of an APF rating of 1000.

The concept of applying a safety factor (an engineering method of de-rating the properties of a material, structure or device in the interest of safety) to respirator protection factor data was suggested by Edwin C. Hyatt, CIH, in a paper he wrote titled Respirators: How well do they really protect? This work was published in the 1984, volume 2, ***Journal of the International Society for Respiratory Protection*** (ISRP).

In the case of WPF studies, OSHA suggests the application of a safety factor of 10 (page 50168). This is because the collection of test data is usually "controlled" to one degree or another. Therefore, WPF studies may not actually represent true workplace conditions and do not take into account misapplication and misuse of respiratory protection equipment.

In the case of SWPF studies OSHA likewise suggests the application of a safety factor. However, in this instance the number 25 is suggested (page 50168). It is assumed that the higher number takes into account the higher degree of control obtained in what is typically a laboratory setting. WPF and SWPF studies require some degree of control as is required in any legitimate scientific experiment.

While WPF studies are quite useful to assess the performance of a respirator in a known, specific workplace setting, SWPF studies are better suited for the purpose of rating the performance of a respirator by virtue of the fact that they are more "controlled".

OSHA also suggests, because of the very nature of Protection Factor data, the 5^{th} percentile be used as a limiting criteria. In essence, the 1987 ***NIOSH Respirator Decision Logic*** (RDL) defined APF as "the minimum anticipated protection provided by a properly functioning respirator to a given percentage of properly fitted and trained users." OSHA discusses the concept of "given percentage" on page 50157. However in this case, OSHA states the "given percentage" implies that some respirator users will not achieve the full APF under workplace conditions. OSHA goes on to state the given percentage usually is about 5%, which is derived from statistical analyses of results from WPF studies (ref. 1987 NIOSH RDL, page 29). In this regard, 5% represents the 5^{th} percentile of the geometric distribution of individual PFs in a given study.

In 1992 Bullard conducted a battery of SWPF studies, witnessed by an independent, qualified third party, to evaluate the efficacy of all its respirators. This study, using safety factors and 5^{th} percentiles, was peer-reviewed and published in the Fall 1994 issue of the ***Journal of the International Society for Respiratory Protection.*** The methods used were similar and equivalent to those employed in the ORC-LLNL study.

In 1994 Bullard petitioned OSHA to grant its Models 77 and 88 abrasive blasting helmet-style respirators an APF of 1000 in light of the then newly published Lead in Construction standard. Because of the way respirators are classified by NIOSH, OSHA expected PAPR and SAR respirators to be positive pressure (PP) devices. For example in the testing requirements for Type C, continuous-flow class respirators the NIOSH respirator certification standard, 42CFR84, makes reference to "The minimum flow of air

required to maintain a positive pressure in the respiratory-inlet covering." At the time, the OSHA regulations indicated that PP devices could achieve APF's of 1000. Therefore, for the 77 and 88 respirators to be assigned a PF of 1000, OSHA wanted proof that they were in fact PP devices, even though they were loose-fitting helmet/hood-style respirators.

Bullard worked with OSHA and Lawrence Livermore National Laboratories (LLNL) to develop the requisite testing protocols for the 77 and 88. Ultimately, OSHA accepted Bullard's test protocols for defining PP.

As a result of the study LLNL performed on Bullard's Models 77 and 88 respirators in 1995, OSHA granted these respirators an APF of 1000 regarding the Lead in Construction standard. By doing this, OSHA placed itself in the position of being a de facto certifying agency for respirators, a position neither it nor NIOSH desired, but found necessary in the absence of an updated APF ruling.

With this new August 2006 rule, it is OSHA's intent to get out of the "letter writing" and de facto respirator certification business. With specific regard to footnote 4, the new ruling now clearly places the responsibility for proper respirator selection on employers (page 50168). It is now the employer's responsibility to evaluate and interpret the respirator manufacturer's evidence and make respirator selection decisions accordingly.

The LLNL study subsequently became the prototype for the ORC study, published in the ***Journal of the American Industrial Hygiene Association*** in 2001. This work was also carried out by LLNL. Like the Bullard study, pressure within the respiratory inlet coverings was measured, recorded and analyzed.

One of the conclusions of the ORC study was that there is no correlation between respirator performance, as reflected by its Protection Factor rating, and positive pressure measured inside the respirator inlet covering (hood/helmet). Therefore, in the new OSHA APF regulation, PAPR's and SAR's are no longer necessarily required to be positive pressure devices in order to be classified with an APF of 1000. As stated on page 50167, "This study indicates that pressure within the respiratory inlet covering is only one of a complex set of factors that determine the protection provided by PAPRs and supplied-air respirators, and should not be considered by itself."

In its Final Rule, OSHA removed from footnote 4 the language that appeared in the original proposed rule which stated that only helmet/hood respirators that ensure the maintenance of positive pressure shall receive an APF of 1000 (page 50168).

The LLNL and ORC studies, as well as those performed in Bullard's laboratory and other similar facilities such as the U.S. Army's Research, Development and Engineering Command (RDECOM) facility in Aberdeen Proving Ground, MD, were/are performed using aerosol detection photometers and generated liquid aerosols of known and controlled concentration high enough to be able to measure elevated PFs.

In summary, when assessing the evidence supplied by the respirator manufacturer in support of that manufacturer's claim of a 1000 APF for its respirator model, an employer should ask the following:

- **Was the data or evidence gathered in the context of a study conducted by an independent, qualified third party?** What experience or qualifications does the third party entity have in the realm of respirator testing? Data gathered and reported by the respirator manufacturer alone should not be given the same weight as that collected and analyzed by reputable, qualified third parties.
- **Was the data gathered in a Workplace Protection Factor study?** If so, were there a sufficient number of observations recorded to allow proper statistical analysis? To achieve an Assigned Protection Factor of 1000 based upon a WPF study, the 5^{th} percentile of the measured protection factors must be equal to or greater than 10,000.
- **Was the data gathered in a Simulated Workplace Protection Factor study (typically in a laboratory setting)?** If so, were there a sufficient number of observations recorded to allow proper statistical analysis? To achieve an Assigned Protection Factor of 1,000 based upon an SWPF study, the 5^{th} percentile of the measured protection factors must be equal to or greater than 25,000.

The fact that some PAPRs and some SARs with hoods or helmets do rate an APF of 1000 while others do not indicates clearly that when it comes to respirator performance, design matters. Unfortunately, NIOSH testing and certification procedures for these classes of respirators do not distinguish between high and low performing products at the present time. It is then left to the manufacturers of the better designed and better performing products to incur the additional expense and time of demonstrating the higher level of efficacy of their respirators to the employers who select them for use by their employees. Through resources such as this White Paper and the references cited herein, we hope that employers will be in a stronger position to evaluate respirator performance evidence provided by respirator manufacturers.

John H. King
Technical Director
September 21, 2006

About the Author

John King has conducted numerous respirator performance studies during his 30+ year career. He has authored many technical papers and contributed extensively to the creation of several national consensus standards. He holds numerous patents regarding inventions for personal protection devices. He may be reached via e-mail at john_king@bullard.com or by calling 859-234-6616, ext. 243.