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Comments regarding

OSHA Docket No. H049C - "Proposed rule; request for comments and scheduling of informal hearings"

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CONTENTS

SUMMARY

- OSHA was mistaken to exclude Effective Protection Factor (EPF) studies from their deliberations.
- EPF studies reveal that respirator non-use in regulated areas occurs even in the presence of full featured respirator protection programs.
- Workplace Protection Factor (WPF) and Simulated Workplace Protection Factor (SWPF) studies do not take into account respirator non-use; therefore, they tend to produce protection factor estimates that are biased high.
- For OSHA to assign a high APFs to a air-purifying respirator requires that OSHA have evidence that the presence of a full featured respirator protection program will result in 100% respirator usage in high exposure (i.e., regulated) areas.
- Large APFs and large personal fit factors - for air-purifying respirators and most workplaces - provide only an illusion of protection. Seconds to minutes of non-use can reduce an impressive protection factor to a dismally low value.
- After consideration of WPF and SWPF studies, EPF studies, and the effect of respirator non-use, an APF of 100 to 250 would be more appropriate for full-facepiece and helmet/hood PAPRs when used in most workplaces (e.g., construction, building renovation, smelters).
- The proposed APF of 1000 for full-facepiece and helmet/hood PAPRs is more appropriate for indoor, stable and controlled operations (e.g., pharmaceutical processes). Such an APF should be permitted only when the employer can guarantee 100% respirator usage in regulated areas and has established such areas using sound science.

These comments were submitted to OSHA by Exposure Assessment Solutions, Inc. as a service to workers, employers, and the occupational health and safety community.

1 Introduction

OSHA (2003) proposed to establish Assigned Protection Factors (APF) for a number of respirator classes. Establishing such APFs, and applying them whenever personal protective equipment (PPE) is needed to control an OSHA regulated substance will, in OSHA's opinion, remove confusion and increase worker protection:

> "The proposed APFs would reduce employee exposures to several section 6(b)5 chemicals..." (OSHA, 2003, p.34083)

However, merely increasing the APF for a class of respirator does not increase actual worker protection, it only changes our perception of worker protection. Below are comments regarding the specific questions posed by OSHA, as well as discussions of the deficiencies of Workplace Protection Factor (WPF) studies and Simulated Workplace Protection Factor (SWPF) studies. Both types of studies, but particularly the SWPF studies, must be throughly critiqued for their weaknesses and biases before OSHA sets APFs based upon their results.

Large APFs for powered air-purifying respirators can easily mislead both employers and employees into thinking that they will actually be realizing protection factors this large or larger. Because large APFs (or even larger personal fit factors) can, under usual working conditions, provide only an illusion of protection, it is entirely possible that workers will end up in higher exposure scenarios and experience higher actual exposures than would result if a lower APF was coupled with feasible controls.

I will argue that an APF of 1000 for any air purifying respirator is reasonable only where OSHA can guarantee that workers wear the respirators 100% of the time when in a regulated area.

2 Comments Regarding the Issues Posed by OSHA

"1. Is the method used by OSHA in developing the proposed APFs appropriate?"

Yes and No. OSHA is obligated to make decisions that take into account the best available information and are conservatively protective of workers (i.e., implement the precautionary principle). OSHA should take into account Effective Protection Factor (EPF) studies. Such studies indicate that in the real world - that is, not the world of contrived and controlled WPF and SWPF studies - workers usually do not wear respirators 100% of the time exposed. The selection of the appropriate APF for a class of respirator should also reflect an understanding of how the respirators tend to be used in hot, strenuous jobs. See Sections 3 and 4.

Recommendations: OSHA should factor in real world conditions, and not rely exclusively on WPF and particularly SWPF studies.

"2. Are there any additional studies that may be useful in determining APFs..."

Yes. OSHA concluded that EPF studies were not relevant to the process of assigning an APF to classes of respirators. However, it is these EPF studies that provide insight into how respirators are used in the real world. In contrast, WPF studies merely inform us about protection factors that can be achieved under perfect or near perfect conditions, using well maintained equipment, and well-trained subjects. For example, see the interesting and revealing letter to the editor by Glindmeyer (1998) where the weaknesses were exposed for a highly-controlled U.S. WPF study of abrasive blasting helmets. This critique applies to any WPF study, which almost by definition is highly controlled and not indicative of *real world* conditions. (See Section 3 for a summary of Glindmeyer's comments.)

Similarly, studies of simulated WPFs (SWPF) tell us virtually nothing about how the rigors and stresses of *real work* under *real conditions* affect workers and their respirator use patterns. The limitations of such contrived studies were noted by OSHA's own consultant - Dr. Ettinger (Exhibit 3-3) - who advised OSHA of the need to consider "human factors" when studying the protection afforded by respirators. I agree. See Section 4 for a summary of one such study of *real protection factors under read conditions* (Spear *et al.*, 2000). An analysis of the study suggests the following:

- The presence of a well run respiratory protection program does not necessarily result in workers wearing respirators 100% of the time when in a regulated area.
- Over the course of a shift workers may accumulate up to 22% of respirator non-use time within regulated areas.

- Periods of non-use when in regulated areas can degrade fairly impressive individual worker quantitative fit factors to dismally low EPFs.

Even the authors of the ORC study of PAPRs and SARs strongly cautioned that their data should not be extrapolated to all work situations (see the published version of the ORC study - Cohen *et al*., 2001). They specifically ruled out construction and other strenuous activities. See Section 3 for more details.

Summary: Neither industry nor OSHA have presented any sound, scientific evidence that the presence of a respiratory protection program - having all the required elements - will ensure that respirators are worn virtually 100% of the time when workers are in regulated areas.

Recommendations: Part of the process of deriving APFs should include an evaluation of our cumulative experience regarding how respirators tend to actually be used in industry whenever a respirator program is in effect.

"3. Are statistical analyses, treatments, or approaches, other those described in Section IV of the proposal, available for differentiating between or comparing the highly variable respirator-performance data?"

Yes. Drs. Nicas and John Neuhaus have updated the Nicas Model in a paper entitled "Variability in Respiratory Protection and the Assigned Protection Factor", to be published soon in the *American Industrial Hygiene Association Journal*. The Nicas Model was proposed in 1995 as a starting point for developing a rational approach to collecting and analyzing WPF data (See Section 6.) However, neither the ANSI respirator committee, the respirator producing industry, nor the respirator using groups (company associations, coalitions, and professional societies) have taken the lead in developing sound, scientific and statistically based strategies for collecting WPF (and EPF) data.

Recommendation: OSHA should obtain a copy of this paper and engage the interested parties in developing a consensus framework for the collection and analysis WPF and EPF data.

"4. ... Is there evidence that a different APF should be provided for these respirator classes [i.e., filtering facepiece respirators]?"

Yes. Drs. Nicas and John Neuhaus have updated the Nicas Model in a paper entitled "Variability in Respiratory Protection and the Assigned Protection Factor", which will be published this year in the *American Industrial Hygiene Association Journal*. Using this model and available data, they concluded that the APF for half-mask respirators should be 5. Their analysis and conclusion are relevant to OSHA's deliberations regarding half-masks.

"7. ... Should OSHA take into account the limitations of the filter and assign an APF of 20 for full facepiece respirators when N95 filters are used."

Yes. The filtering efficiency of a particular type of air-purifying respirator would seem to lead to a maximum possible APF: max APF = 1 / (1 - efficiency). As shown in Table I, this results in a maximum APF of 20 for N95 filters, and a maximum APF of 333 for N100 filters. However, since the nominal filtering efficiency is that for the most penetrating particle sizes - i.e., particles roughly 0.5 µm in aerodynamic diameter - the filtration efficiency against most mechanically generated industrial dusts or particulates is probably greater.

Table I: Filtration efficiency and the maximum possible APF (as a function of filtration efficiency).

Filter Type	Assigned Filtration or Capture Efficiency	Maximum APF = 1/ (1-Efficiency)
N95	0.95	20
N99	0.99	100
N100	0.997	333

"10. ... What other limiting factors should OSHA include as examples in this proposed paragraph?"

If OSHA insists on assigning an APF of 1000 for certain air-purifying respirators, then it should directly address the IDLH issue. With an APF of 1000 the MUC for many substances will approach or exceed the IDLH (see NIOSH, 2003 for IDLH information).

Recommendation: OSHA should formally address the issue by specifying that an upper bound on the MUC is some percentage of the IDLH, say no more than 25%.

> **"11. ... (a) Should OSHA expand the definition and application of MUC to hazardous substances that it does not regulate?"**

Yes. According to 5(a) of the Occupational Safety and Health Act of 1970:

> "Each employer (1) shall furnish to each of his employees employment and a place of employment which are free from <u>recognized hazards</u> [emphasis added] that are causing or are likely to cause death or serious physical harm to his employees; (2) shall comply with occupational safety and health standards promulgated under this Act.

Congress clearly and distinctly differentiated between "recognized hazards" and the OSHA standards. An employer is obligated to protect workers against recognized hazards - this is the basis for the "general duty clause" - *as well as* comply with the OSHA standards. A "recognized hazard" can be, and usually is, defined as any substance or mixture of substances recognized by authoritative organization (such as the ACGIH or AIHA) as potentially hazardous, described as being hazardous in its MSDS, recognized by the industry or employer as being hazardous (e.g., proprietary chemicals, ingredients, or chemical intermediates), or reliably described as hazardous in the peer-reviewed literature. Furthermore, according to 29 CFR 1910.1200 (Hazard Communication) a "hazardous chemical means <u>any chemical</u> [emphasis added] which is a physical hazard or a health hazard". Section (d)(3)(ii) clearly indicates that any chemical listed in the ACGIH booklet are by definition a hazardous chemical.

Furthermore, the existing respiratory protection regulations - 29 CFR 1910.134 - do not distinguish between regulated and non-regulated substances when admonishing the employer to use appropriate respiratory protection whenever engineering and other controls do not adequately reduce exposures:

> "(a)(1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.
>
> (a)(2) Respirators shall be provided by the employer when such equipment is necessary to protect the health of the employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program which shall include the requirements outlined in paragraph (c) of this section."

Recommendations: OSHA should strongly indicate - either by regulation or by repeated emphasis in the preamble to the final standard and in all respirator guidelines - that these requirements also apply to overexposure scenarios involving unregulated substances.

> **"11. ... (b) Should the Agency require employers to determine MUCs for substances that have no OSHA PEL ... and to base respirator selection on such a determination?"**

Yes. This follows from my answer to the above question.

> **"11. ... (c) For hazardous substances that OSHA does regulate, should it require employers to comply with the MUC values developed by NIOSH when these values are lower than the calculated MUC values (i.e., MUC = APF x PEL)?"**

No. However, the NIOSH MUCs take into account the substance IDLH and so should be consulted by employers when selecting respirators. But as I recommended above, OSHA should develop guidance or requirements for those situations where the calculated MUC exceeds some fraction of the IDLH.

Recommendations: OSHA should strongly indicate by repeated emphasis in the preamble to the final standard and in all respirator guidelines that employers would be well advised to consult and use the NIOSH MUC recommendations.

3 Limitations of WPF Studies and Simulated WPF (SWPF) Studies

3.1 WPF Studies

WPF studies are useful in that they indicate what we might be able to achieve in the perfect workplace, with perfectly trained employees, and a perfectly knowledgeable and ever vigilant employer. However, conditions during WPF studies tend to be contrived, and hardly representative of the usual workplace where a respiratory protection program is in effect. For example, Glindmeyer (1998) in a letter to the editor mentioned the following "limiting factors" for a specific WPF study of abrasive blasting respirators:

- respiratory protective equipment was well maintained
- operation of the respiratory protective equipment was optimized
- experts were on hand to ensure that all standard operating procedures were followed and to ensure that the equipment was perfectly maintained
- the work regimen was contrived, of shorter than usual duration, and not representative of a normal shift
- work tasks were not representative of the varied positions and stresses of actual work.

Conclusions: WPF studies tend to give us an overly optimistic, even biased view of the level of protection that real workers obtain from respirators in real workplaces.

Recommendations: OSHA should also review the numerous Effective Protection Factor (EPF) studies in order to understand how respirators tend to be used in *real* work environments.

3.2 SWPF Studies

In recommending an APF of 1000 for PAPRs, OSHA relied heavily on Exhibit 3-4-1 - the ORC study (date not indicated). The peer-reviewed, published version of this study (Cohen *et al*., 2001) contained additional cautionary language that OSHA should review. For example:

> "This study was conducted indoors where there were no significant air currents that might affect the performance of these respirators, and these results might not be applicable to certain uses outdoors (e.g., lead removal from bridges). Furthermore, the estimated APFs are based on users <u>properly wearing respirators 100% of the time</u> [emphasis added], and a significant loss of protection would result if respirators were not properly worn even for brief periods of time (e.g., 5 min out of an entire work shift)."
>
> "However, some workplace activities may produce exercises that are more challenging to the fit of a respirator than those in this study."

The Cohen *et al*. study was basically aimed at evaluating the use of PAPRs in well controlled, air-conditioned, indoor work environments (e.g., those found in the manufacture of pharmaceuticals). They did not do a field study where the workers engaged in strenuous activities. They did not evaluate whether or not - under real world scenarios to include construction and building renovation work during hot weather - an employer can induce workers to wear PAPRs <u>100% of the time exposed</u>.

> "...these results might not be applicable to certain uses outdoors (e.g., lead removal from bridges)."
>
> "...a significant loss of protection would result if respirators were not properly worn even for brief periods of time (e.g., 5 min out of an entire work shift)."
>
> Cohen *et al*. (2001)

Dr. Ettinger, a consultant to OSHA, expressed similar reservations in a report to OSHA (Exhibit 3-3). OSHA summarized his recommendations (OSHA, 2003, p.34049):

> "For example, he suggested that the additional exercises in the more recent study (ORC, 2001; Ex. 3-4-2) did not adequately represent normal or extreme work situations."

Conclusion: Contrived studies - WPF or SWPF - have limitations which must be acknowledged and factored into the selection of APFs. The next section describes one such study.

4 Importance of Effective Protection Factor (EPF) Studies

Although Dr. Ettinger recommended that “human factors” (OSHA, 2003, p.34049) also be taken into account when setting APFs, OSHA in this proposal purposefully chose to ignore “human factors” - both employer-based and worker-based - by eliminating studies of “Effective Protection Factors” (EPF). Instead, OSHA states that the proposed APFs are for the situation where all the elements of employer-based respiratory protection program are in place and functioning properly. While unstated, OSHA must also have assumed that respirators will be worn 100% of the time whenever a worker is within a respirator regulated area and that the employers will use sound science to establish the boundaries of the regulated areas. Let us review a single study of EPFs for insights into how respirators are used in the real world. Later we will examine the potential effect that seconds to minutes of respirator non-use may have on individual worker protection factors.

In the introduction to a published study of EPFs at a lead smelter, Spear *et al*. (2000) stated that

> “It cannot be assumed that the numerical values of the APFs represent the absolute level of protection that would be achieved for all workers in all jobs against all respiratory hazards. Additionally, fit factors determined by employers on their own workers in a laboratory or office-type setting, may not reflect the true protection being provided under <u>actual working conditions</u> [emphasis added].”

Spear *et al*. (2000) studied workers that entered regulated areas where all were required to wear either negative-pressure half-masks or positive-pressure (PAPR) half-masks. All workers were enrolled in a respirator protection program, and were required to achieve a personal fit factor of 100 or more. But despite the fact that the company had a well run respiratory protection program, clearly demarcated respirator use areas, and worker quantitative fit factors that were impressively high, the EPFs were abysmally low (see their Figures 1 and 2). In fact, the majority of the EPFs for both the negative-pressure and the positive-pressure half-masks were less than the ANSI APFs of 10 and 50.

Data such as those presented by Spear *et al*. (2000) clearly beg the question: Should APFs be established based solely upon the performance studies of respirators where all conditions extraneous to the respirator are nearly ideal, or should EPF studies also be considered?

OSHA indicates in Footnote 2 of Table 1 of the proposed changes that the APFs apply only when the employer has in place a “continuing, effective” respirator protection program. In order for a an APF of 1000 to be assigned to full-facepiece and helmet/hood PAPRs OSHA must have evidence of the following:

- the employer correctly determines and identifies the mandatory respirator use areas - referred to as “regulated areas” in several of the 6(b) standards,
- workers within those regulated areas wear their respirator 100% of the time.

As the documentation currently stands, OSHA has presented absolutely no evidence that having a “continuing, effective” program equates with virtually 100% respirator usage in regulated areas where “... an employee's exposure to airborne concentrations of [a substance] exceeds or can reasonably be expected to exceed either the 8-hour TWA PEL or the STEL” (adapted from 29 CFR 1910.1052 (e)(1) Methylene Chloride). This is a critical issue if OSHA proceeds with promulgating an APF of 1000 for PAPRs. This is because if an employer actually exposes workers to concentrations that hundreds of times greater than the PEL, then any appreciable period of non-use will result in a substantial worker exposure.

Spear *et al*. (2000) estimated that the proportion of the time spent within regulated areas ranged when the respirator was not worn was between 5.6% to 22% for the workers studied (percentage varies depending upon the assumptions in the calculations). And these estimates were for a well established, seemingly well run program (Spear, 2003). The authors offered four reasons for respirator non-use:

(1) workers donned the respirators when in “close proximity” to the process,
(2) removed the respirators when walking away from the process,
(3) removed the respirators when attempting to communicate with fellow workers, and
(4) failed to don the respirator when simply “walking through” the process area.

While no doubt some of these factors can be modified by training or increased supervisor vigilance, it is highly doubtful that 100% respirator compliance is possible for hot processes, outdoor environments during summer months, activities where the work is strenuous or accurate communication at a distance is critical, and so on. And anyone would agree who has worn a respirator of any sort in a warm environment under strenuous conditions. (OSHA should also review Salazar *et al*. (2001) for background on worker concerns when frequently required to use respirators.)

To illustrate my concern, let us take the low end of the Spear *et al*. - $\theta = 0.05$, or 5% of the workshift (where θ refers to the cumulative fraction of the exposure period that the respirator is not worn) - and examine the potential effect it might have on both the APF and an individual worker's fit factor. If we assume a normal 8-hour work shift during which the respirator was supposed to be worn, then $\theta=0.05$ translates into 24 minutes of non-use (spread throughout the workday). If we also assume that the worker realized a protection factor only equal to the APF, then the protection factor was, because of periods of non-use, degraded to a fairly unimpressive 20 (round upwards from 19.627). (See Section 5 for the basis for this calculation.)

Well, let us assume that the *worker actually had a personal fit factor of something really big* - say 250,000 (the maximum SWPF used in the ORC/Cohen *et al*. study). (This assumption is actually the basis for both industry's and OSHA's confidence in an APF of 1000 for PAPRs.) Unfortunately, 5% non-use degrades even a WPF of 250,000 to a much less impressive EPF of 20 (rounded upwards 19.998). While this result seems counterintuitive, it is entirely possible for two very different worker protection values to degrade to virtually identical values after just a few minutes of respirator non-use (see Section 5).

Unfortunately, 5% non-use degrades even a WPF of 250,000 to a much less impressive EPF of 20 ...

In conclusion, in real world situations where real workers are wearing respirators that can easily be removed or the face seal easily broken - e.g., half-mask, full-facepiece, or helmet style respirators - and are doing real work under real condition - e.g., strenuous and hot conditions construction, tunneling, mining, building renovation, or smelter work - large APFs or worker quantitative fit factors provide only an *illusion* that workers are protected. OSHA should recognize that merely increasing the APF does not increase worker protection, and as will be discussed below may very well reduce actual worker protection.

Conclusions:

- The presence of a well run respiratory protection program does not mean that workers will wear respirators 100% of the time when in a regulated area.
- Over the course of a shift workers may accumulate a total of 5.6% to 22% of respirator non-use time within regulated areas.
- Periods of non-use when in regulated areas can degrade fairly impressive individual worker quantitative fit factors to dismally low EPFs.

Recommendations: OSHA should evaluate the effect that respirator non-use will have on the hoped for levels of protection, particularly for air-purifying respirators where OSHA is being pressured to assigned large APFs. In the next section we demonstrate how large WPFs can rapidly degrade to unimpressive protection levels given seconds to minutes of non-use.

5 Large WPFs and the Illusion of Protection

In OSHA's proposal for specifying APF values for the various classes of respirators OSHA is laudably conservative in assigning APFs to those classes of respirators where there are few or conflicting studies regarding the expected WPFs. However, regarding full-facepiece and helmet/hood PAPRs, OSHA recommended an APF of 1000 on the strength of a few well-controlled WPF and SWPF studies where the study authors concluded, after analyzing the distribution of observed WPF and SWPF values, that the APF for these types of respirators should be 1000 or more, but not without noting that the their *data* also support much larger APFs. This suggests that they were being truly conservative in recommending an APF of 1000. And I would agree - but only for specific, well-controlled tasks in well-controlled facilities and employing well-trained workers. For other *real world* scenarios, these large WPFs and SWPFs provide only an illusion of protection.

The data collected by the authors of the ORC/Cohen *et al*. study may indeed point in the direction of large APFs for certain stable operations where the regulated area is obvious or can be established with scientific precision, transition zones or respirator change areas can be easily established and maintained, tasks and activities are not strenuous, and the air is conditioned - e.g., pharmaceutical processes. However, a common sense analysis of large APFs and WPFs would suggest that an APF considerably less than 1000 is more appropriate for all other operations and processes. In many outdoor situations - e.g., construction, tunneling, bridge repair and repainting, building renovation activities such as tuck pointing - exposures to toxic agents can (without attempts at control) exceed the OSHA PEL (or ACGIH TLV) by several orders of magnitude. Use of a full-facepiece respirator or PAPR with a nominal APF of 1000 might seem to be more than appropriate in these situations. However, as we saw earlier, even with a well established company respiratory protection program, requirements for regulated areas, and high worker awareness (e.g., see Spear *et al*., 2000) the Effective Protection Factor (EPF) can be considerably less than both the workers' fit factor and the nominal APF. Spear *et al*. (2000) found in a study of EPFs at a lead smelter that the majority of the 47 workers had EPFs less than the respirator APFs and considerably less than the individual worker quantitative fit factors. They observed that workers "removed the respirators as they walked away from the furnace" or "to communicate with fellow workers". They used the following equation to approximate the fraction of the workshift that each worker failed to wear their respirator in regulated areas:

$$EPF = \frac{WPF}{\theta \cdot WPF + (1 - \theta)}$$

The derivation is in Appendix A. This equation is plotted in Figure 1 for various WPF values. The curves show the relationship between the EPF and number of minutes of non-use. The remarkable feature of this graph is that it only takes seconds to minutes of non-use in a high exposure area (i.e., a regulated area such as specified in the OSHA 6(b) standards) to degrade a wonderfully impressive WPF to a dismally low EPF. For example, in the peer-reviewed, published version of the ORC study (see Cohen *et al*. 2001) the authors estimated that the 5th percentile SWPF value for several PAPR models was greater than 250000. Yet a mere six seconds (i.e., 0.1 minutes) of non-use in a high exposure area degrade a protection factor of 250000 to an EPF of less than 5000. A full minute of non-use (perhaps accumulated over the entire shift) would degrade the protection factor further to an EPF of 480. Ten minutes of non-use degrades what was an impressive protection factor to a mere 48. Under such circumstances the fact that the PAPR has an APF of 1000 will prevent workers from experiencing substantial exposures if the ambient exposures are hundreds of times the exposure limit, but below the MUC of 1000·PEL.

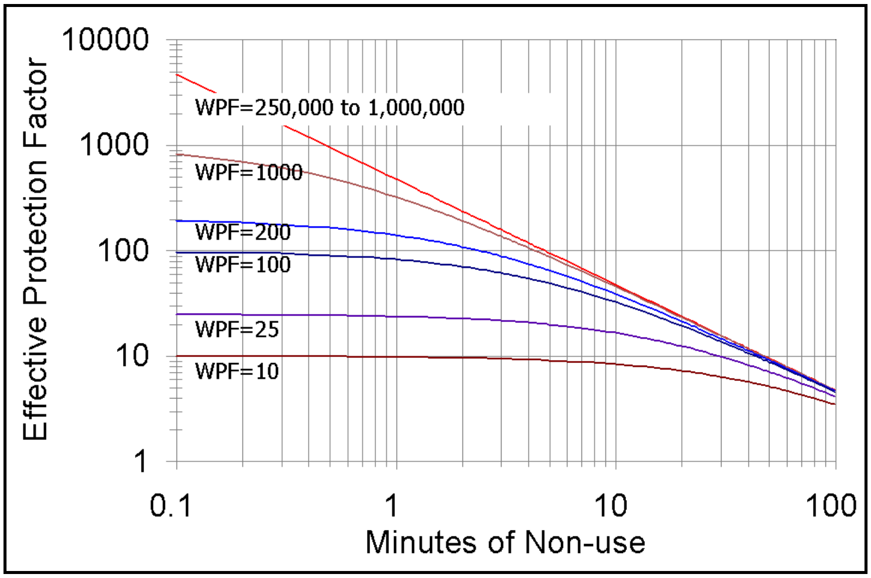

Figure 1: The EPF as a function of a worker's WPF and the number of minutes of non-use when in regulated areas. Seconds to minutes of non-use can degrade a phenomenally high WPF to a much less impressive EPF.

Even if the true workplace protection factor was 1,000,000, it would degrade to virtually identical values after the same periods of non-use. Note that 10 minutes of non-use is only 2% of the work shift, far less than the 5.6% to 22% percent non-use time estimated by Spear *et al*. (2000) for a real world lead smelter. Could it be that in real work settings - i.e., not contrived laboratory chamber settings - real workers will tend to not use a respirator some appreciable fraction of the shift? If so, then the effective protection afforded by respirators can easily be a mere fraction of the rated APF or personal fit factor. In summary, there is little practical difference between WPFs of 1,000,000, 250,000, 1000, or 100 after five to ten minutes of non-use in a regulated area.

To examine this further, we can devise equations for calculating the number of non-use minutes necessary to reduce the WPF (or personal fit factor) to 1/2, 1/10, 1/100, or 1/1000 the original value (see Appendix B for the derivations):

$$T_{\frac{1}{2}} = \frac{480}{WPF - 1} \; minutes \qquad \text{for WPF > 2}$$

$$T_{\frac{1}{10}} = \frac{4320}{WPF - 1} \; minutes \qquad \text{for WPF > 10}$$

$$T_{\frac{1}{100}} = \frac{47520}{WPF - 1} \; minutes \qquad \text{for WPF > 100}$$

$$T_{\frac{1}{1000}} = \frac{479520}{WPF - 1} \; minutes \qquad \text{for WPF > 1000}$$

In summary, there is little practical difference between WPFs of 1,000,000, 250,000, 1000, or 100 after five to ten minutes of non-use in a regulated area.

The above equations were used to calculate the entries in Table II. We see that only seconds to minutes of non-use in a regulated area are required to substantially degrade the expected protection factor. Knowing that respirator non-use is commonplace for some fraction of the time spent in and around regulated areas, even where a "continuing, effective" respirator protection program is in effect, it is difficult to conceive of OSHA assigning an APF of 1000 to PAPRs. OSHA has a mandate to protect workers, and to set an APF at 1000 for this class of respirators without data to demonstrate that a "continuing, effective" program equates to 100% respirator usage is not justified.

Table II: Number of respirator non-use minutes within a regulated area, out of a normal 8-hour workshift, required to degrade an WPF (or personal fit factor) to half, one tenth, one hundredth, or one thousandth the original value.

WPF	**Non-use Time Resulting in 1/k · WPF (in minutes)**			
	1/2	**1/10**	**1/100**	**1/1000**
10	53.3	--	--	--
100	4.8	43.6	--	--
1000	0.5	4.3	47.6	--
10,000	0.05	0.4	4.8	48.0
250,000	0.002	0.02	0.2	1.9
1,000,000	0.0005	0.004	0.05	0.5

6 Comments on the Nicas Model

Dr. Mark Nicas was commissioned by OSHA to develop a "statistical method for deriving APFs" (OSHA, 2003, p.34044). Data collection methods at that time focused on the measurement of a single WPF value for each worker in the study, and the determination of the lower 5th percentile WPF from a relatively simple analysis of the aggregated data. In contrast, Dr. Nicas proposed that a protocol for a WPF study involving a specific respirator require the collection of several WPF values from each worker, so that both sources of variability - WPF variation from worker to worker and day-to-day WPF variation for each worker - could be evaluated and factored into the selection of an APF. Nicas first suggested this approach in 1987 by recommending that "the required study design is to have at least [emphasis in the original] 4 replicate WPF's per user" (Nicas, 1987). The importance of replicate measurements was later demonstrated by Galvin, Selvin, and Spear (1990) in a study of the variability in WPFs. They concluded that "observation of between-worker and within-worker variability in protection indicates that both sources of variability have to be taken into account".

In a commissioned critique of the Nicas proposal, the reviewers (Exhibit 1-182-1) concluded that "the Nicas Report is fundamentally sound" and go on to recommend "that a major research program be conducted to develop appropriate methods and data that can be used to assign reliable protection factors in the future". Unfortunately, neither the ANSI respirator committee, respirator manufacturers, nor the respirator using industries and associations followed up on these recommendations to develop basically a consensus method for collecting and analyzing WPF data for use in assigning APFs. If they had done so, OSHA might have more and better data, collecting using principles of sound science. As it is, the process of assigning APFs is less science-based that it should be, and more industry-professional judgment-based than is perhaps appropriate.

OSHA should be aware that Drs. Nicas and John Neuhaus have updated the Nicas Model in a paper entitled "Variability in Respiratory Protection and the Assigned Protection Factor", to be published soon in the *American Industrial Hygiene Association Journal*.

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Appendix A

Let

$$EPF = \frac{C_o}{C_w} \qquad \text{Equation 1}$$

where C_o indicates the average concentration during a specific shift;
C_w refers to the average concentration experienced by the worker during a specific shift.

The worker concentration C_w is function of (a) the external (to the respirator) exposure, (b) the actual workplace protection factor (WPF) for a specific worker (when wearing a respirator for 100% of the time exposed), and (c) the cumulative fraction (θ) of the shift spent where the worker had removed the respirator or broken the face-to-respirator seal:

$$C_w = \theta \cdot C_o + (1 - \theta) \cdot \frac{C_o}{WPF} \qquad \text{Equation 2}$$

The worker concentration C_w reflects both exposures during that period of the shift when the respirator is worn and the remainder when the respirator is not used. A worker may remove the respirator as soon as they perceive that they are out of a high concentration zone, when they have left a "regulated area", when attempting to converse with fellow workers when in a regulated area, or because physical demands or the heat of the operation or environment make wearing a respirator unbearable for extended periods.

Substituting Equation 2 into Equation 1 and rearranging results in the following equation:

$$\boxed{EPF = \frac{WPF}{\theta \cdot WPF + (1 - \theta)}} \qquad \text{Equation 3}$$

As θ approaches 0, indicating little non-use, the EPF approaches the WPF. As θ approaches 1, indicating very little use, the EPF approaches one. Equation 3 provides an estimate of the EPF given any particular worker fit factor and time of non-use.

Obviously, there are various assumptions built into this equation, chief of which is the assumption that contaminant exposures across the shift and throughout the respirator controlled area vary in a random manner. But as is, Equation 3 provides us a reasonable approximation of the effect that respirator non-use will have on a worker's WPF.

Appendix B

Using Equation 3 from Appendix A, we can derive an equation to calculate the approximate non-use time required to result in an EPF that is one kth the WPF (that would result if the worker wore the respirator 100% of the shift or 100% of the time exposed). For example, how many minutes are required to degrade a WPF to an EPF that is half the expected value (k = 2). We set Equation 3 equal to 1/k·WPF, solve for θ (the fraction of the shift that the respirator is either not used or used improperly), and then convert θ to units of minutes:

$$EPF = \frac{WPF}{\theta \cdot WPF + (1 - \theta)}$$

$$\frac{1}{k} \cdot WPF = \frac{WPF}{\theta \cdot WPF + (1 - \theta)}$$

Solve for θ:

$$\theta = \frac{k - 1}{WPF - 1}$$ where θ is the fraction of an 8-hour shift

Substitute $T_{1/k}$/480 for θ to convert to time units of minutes:

$$\frac{T_{\frac{1}{k}}}{480 minutes} = \frac{k - 1}{WPF - 1}$$

$$\boxed{T_{\frac{1}{k}} = \frac{k - 1}{WPF - 1} \cdot 480 \ minutes}$$ where 1 < k < WPF Equation 4

Equation 5 can be used to generate specific equations to calculate approximate non-use time where the EPF is 1/2, 1/10, 1/100, and 1/1000 the nominal WPF:

$$T_{\frac{1}{2}} = \frac{480}{WPF - 1} \ minutes$$ for WPF > 2

$$T_{\frac{1}{10}} = \frac{4320}{WPF - 1} \ minutes$$ for WPF > 10

$$T_{\frac{1}{100}} = \frac{47520}{WPF - 1} \ minutes$$ for WPF > 100

$$T_{\frac{1}{1000}} = \frac{479520}{WPF - 1} \ minutes$$ for WPF > 1000