

FORUM

Some Considerations in Defining the "Protection Factor"

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In the Forum section of the Fall 1994 *JISRP*, R.M. Howie identified the need to statistically define the "protection factor." Because the latter term appears equivalent to the term "Assigned protection factor" (APF) used in the United States, I will hereafter use APF as synonymous with Mr. Howie's protection factor. I entirely agree that the APF needs to be statistically defined, and that the *JISRP* is an excellent forum for the discussion, although I believe that the definition will end up being more complex than Mr. Howie suggests.

To summarize my understanding of Mr. Howie's view, there exists a distribution of workplace protection factor (WPF) values experienced by different respirator wearers, and the APF should be equated with some percentile of this distribution. For example, if the APF = 10 for a negative-pressure air-purifying halfmask, perhaps 95% of wearers should achieve a WPF of 10 or greater, in which case it is explicitly recognized that 5% of wearers achieve a WPF less than 10. The future consensus definition of the APF for a respirator class involves specifying the appropriate percentile (e.g., 5%, 10%, 25%) and the corresponding WPF value (e.g., 5, 10, 20).

Now according to Mr. Howie's description, it is assumed that the WPF experienced by a given wearer is a constant value. That is, if a wearer achieves a WPF of 25 during one wearing, he is assumed to achieve a WPF of 25 during all other wearings. However, published WPF data do not support this assumption. Instead, the data indicate

that for a given wearer the WPF varies from wearing to wearing, and in the U.S. literature it is generally assumed that an individual wearer's WPF distribution is lognormal.

This complication wouldn't be so bad if it were also true that all wearers experience an identical distribution of WPF values. In this case, the APF could be defined as the minimum WPF value achieved by every wearer during some specified proportion of wearings. However, published WPF data do not support the assumption of homogeneity among wearers. Instead, the data indicate that different wearers have different WPF distributions. The consequence of this between-wearer variability is that a given numerical APF value does *not* represent the same percentile of each wearer's WPF distribution.

In a number of published articles and talks presented over the past ten years, I have suggested that a classical lognormal analysis of variance (ANOVA) model is a good descriptor of WPF variability in a wearer population. To explain, every wearer is assumed to have a lognormal distribution of WPF values. Each of these individual distributions has the same geometric standard deviation value, but has a unique geometric mean value. Further, these geometric mean values vary lognormally across the wearer population. In summary, there is lognormal within-wearer variability in WPF values from wearing to wearing, and lognormal between-wearer variability in geometric mean WPF

values. A detailed explanation of the lognormal ANOVA model, and of its practical consequences with regard to inhaled contaminant concentrations, has been previously published (*Am. Ind. Hyg. Assoc. J.* 53:411–426, 1992).

A mathematical result of this structure is that if one selects ten or so wearers in a group, makes WPF measurements over several respirator use periods for each chosen wearer, and then aggregates all these WPF values, the aggregate data will appear to be lognormally distributed. In fact, most U.S. investigators analyze their WPF data in an aggregate fashion and, as Mr. Howie noted, usually compute a 5th percentile WPF value as a summary statistic. Moreover, these investigators commonly suggest that the APF value be set equal to this aggregate 5th percentile WPF value.

Unfortunately, due to the underlying between-wearer variability which is improperly treated in the aggregate data analysis, this suggested APF value does *not* represent every wearer's 5th percentile WPF value, *nor* does it signify that only 5% of wearers have 5th percentile WPF values less than the APF value. In effect, an APF equated with an aggregate 5th percentile WPF value has no clear statistical meaning with regard to worker protection.

Given the general reluctance of occupational hygiene regulator agencies to tackle complicated statistical issues, and to formally endorse a politically controversial idea like an acceptable fraction of inadequately protected respirator wearers, I believe that the *JISRP* is the only practical forum in which to openly discuss the issues and perhaps arrive at some consensus.

To help begin the process, I propose that the APF be equated with the Y-percentile (to be determined) of the between-wearer distribution of the 5th percentile WPF values, where the latter distribution is estimated from appropriate WPF data analyzed by a lognormal ANOVA. Note that if every wearer has a unique geometric mean WPF value, every wearer has a unique 5th percentile WPF value. The proposed definition properly accounts for within-wearer and between-wearer variability, signifies that 100-Y percent of respirator wearers experience $\geq 95\%$ of WPFs *above* the APF value, and signifies that Y percent of respirator wearers experience $> 5\%$ of WPFs *below* the APF value. Given the toxicological properties of the air contaminant, a 5th percentile WPF value may not be the most appropriate measure of protection for an individual worker, but at least the APF will have a clear statistical definition that tends to be health-conservative.