

conclusions. For a detailed explanation of the methodology and rationale used in the analyses, refer to Brown's reports in the docket (Exs. 5–1, 5–2).

OSHA reviewed the available WPF studies for possible inclusion in Brown's analyses. Early in this review process, the Agency decided to exclude WPF studies with a gas or vapor workplace challenge agent because: The preponderance of studies were conducted in workplaces with particulate challenges; gas/vapor studies did not provide any further insight or clarification regarding sources of variability in WPF studies (most likely, gas/vapor studies add variability to the data such as the effects of humidity on sampling media collection and desorption efficiencies); and pulmonary

elimination differs between gases/vapors and particulates. Therefore, OSHA decided to analyze only WPF studies using particulate challenge agents. The Agency evaluated those studies initially selected for further analysis for compliance with the requirements of OSHA's Respiratory Protection Standard (29 CFR 1910.134), as well as completeness of the data. The Agency compiled a list of review items to use in evaluating each study (Ex. 5–5).

OSHA then divided the remaining studies into two categories: Half-mask negative-pressure air-purifying respirators (APRs) and atmosphere-supplying respirators (PAPRs and SARs). This procedure resulted in 22 APR studies and 16 PAPR/SAR studies

for analysis. OSHA placed a list of these studies, and their respective respirators, in the docket (Ex. 7–4). Brown subsequently identified 14 APR studies and 13 PAPR/SAR studies for further analysis (see Exs. 5–1 and 5–2 for more information on the evaluation criteria).

Brown's analyses divided the respirators used in these studies into separate respirator classes. The analyses divided APRs into 5 classes, listed below in Table 1. As this table shows, Brown's analyses separated filtering facepieces into four classes based on the characteristics listed under the Description column heading, with the fifth class comprised of elastomeric facepiece APRs.

TABLE 1.—HALF-MASK APR CLASSES

Class	Type	Description			
		Adjustable head straps	Exhalation valve	Double shell construction	Foam ring liner
1	Filtering facepiece
2	Filtering facepiece	X	X
3	Filtering facepiece	X	X	X
4	Filtering facepiece	X	X	X	X
5	Elastomeric facepiece.				

In addition, Brown's analyses divided PAPRs into five classes and SARs into two classes, as shown in Table 2.

TABLE 2.—PAPR AND SAR CLASSES

Class	Type	Description
1	PAPR	Loose-fitting facepiece.
2	PAPR	Loose-fitting facepiece with hood and/or helmet.
3	PAPR	Hood and/or helmets—not loose-fitting.
4	PAPR	Tight-fitting half-mask facepiece.
5	PAPR	Tight-fitting full facepiece.
6	SAR	Loose-fitting.
7	SAR	Hood or helmet.

Later in the analyses, Brown further divided these classes according to class of respirator, study, and challenge agent (CLSA). This division resulted in 26 CLSAs for the APRs and 14 CLSAs for the PAPRs/SARs.

The data from the WPF studies consisted of simultaneous measurements of the challenge agent concentration inside the respirator facepiece (*i.e.*, concentration inside or C_i) and outside the respirator facepiece (*i.e.*, concentration outside or C_o) in the ambient workplace atmosphere. Corresponding C_o and C_i measurements can be used to calculate the workplace protection factor ($WPF = C_o/C_i$) or

penetration of the contaminant into the respirator ($PEN = C_i/C_o = 1/WPF$). The APR studies had a total of 917 data pairs, while the PAPR/SAR studies provided 443 data pairs.

1. Half-Mask APRs

In the first phase of his analysis, Brown statistically analyzed the data for half-mask negative pressure APRs, both filtering facepiece and elastomeric APRs, using the following three approaches: (1) Pooled the data within classes, corrected the data for the positive relationship found between WPF values and increasing C_o , and compared the differences in WPF statistics between classes; (2) conducted an intra-study analysis of the performance of two different classes of respirator used against the same contaminant under similar workplace conditions; and (3) divided the data into class-study-agent combinations, and evaluated WPF as a function of C_o . The following sections discuss these approaches in detail.

Approach 1. Brown's initial approach was to determine if he could pool the data within each respirator class and estimate the fifth percentile WPF for that respirator class; he then tested for differences in WPFs between the respirator classes. He divided and analyzed the data by study, treating the

data from each study as a homogeneous sample arising from the same parent distribution. Then he examined the data in each study for a Co effect, and constructed a scatterplot of $\ln(WPF)$ versus $\ln(C_o)$ for each respirator class. In doing so, he treated extreme or poorly fitting data as outliers and removed them from the analysis. He subsequently derived a linear regression of $\ln(WPF)$ on $\ln(C_o)$ for each study, and extrapolated from the observed range to the entire range of C_o values in all of the data. The positive slopes, which he found for most classes, showed that $\ln(WPF)$ increased as $\ln(C_o)$ increased. In addition, the regression lines were well mixed, indicating that studies within the same respirator class varied more than anticipated. This result indicated that variability occurring within respirator classes could obscure differences between respirator classes.

These studies collected data over different ranges of C_o . Therefore, to compare the WPFs observed in the studies, Brown corrected the WPF values for all studies, using a common C_o adjustment factor. He pooled the adjusted WPFs by class, and then plotted the cumulative distributions to determine if he could identify differences between respirator classes, despite intra- and inter-study differences. Finding no differences