

to challenge the fit of a respirator (sedentary versus high exercise work)” (Ex. 1–182–10).

4. Using a Conservative Criterion for Setting APFs

Five commenters stated that Nicas’ criterion for setting APF values was overly conservative. The Dow Chemical Company (Dow) stated that the Nicas approach “would result in protection factors which are very conservative” (Ex. 1–182–2), while 3M believed that OSHA’s use of Nicas’s recommendation would result in a major change in the pattern of respirator use (Ex. 1–182–5). NIOSH commented that the approach may result in very low APF estimates because of high WPF variability, and that while the approach would derive more conservative (*i.e.*, more protective) APFs, its use for “WPF studies with small sample sizes * * * could result in APF estimates less than or equal to 1.0 (APF values less than 1.0 are meaningless)” (Ex. 1–182–3). Drs. Rappaport and Kupper stated that only weak precedence existed for Nicas’ use of 95th percentiles to define APFs, and suggested that other percentiles (*e.g.*, the 90th percentile) would be more practical to implement (ISEA, Ex. 1–182–1). Finally, CMA believed that the proposed criterion rated “all respirators on the lowest protection achieved by the lowest performing person” (Ex. 1–182–7).

5. APFs Based on a Contaminant’s Toxicity (Acute Versus Chronic Toxicants)

Dr. Nicas proposed that two APFs be assigned to a respirator, depending on its use against either a chronic toxicant or an acute toxicant. Four commenters remarked on the feasibility and effects of this approach. NIOSH commented that “defining acceptable protection against short-term exposures is very complex * * *.” (Ex. 1–182–3). 3M commented that dual APFs would be confusing to the user community and workers, and would make program management difficult (Ex. 1–182–5). CMA provided similar comments, and noted that many materials have both chronic and acute effects (Ex. 1–182–7). ORC believed that:

* * * different APFs for different contaminants or types of exposure is not appropriate. Occupational exposure standards should have adequate safety factors which are based on the health outcome (*e.g.*, irritation, systemic toxicity, carcinogenicity) of exposure. (Ex. 1–182–10)

While Drs. Rappaport and Kupper stated that Nicas’ argument about respiratory protection for substances with chronic effects was logical, they

regarded the question of how to deal with acutely toxic substances as unresolved (Ex. 1–182–1).

6. Distribution of Contaminant Concentrations

Two participants believed that it was necessary to incorporate information on the variability of ambient exposure concentrations, as well as the maximum anticipated concentration, when discussing respirator selection. CMA stated that since an employee’s exposures will vary from day to day, employers should select respirators with maximum use limits well above the mean exposure levels to ensure “that there is less than 5% probability of exposures above the maximum use limit of the respirator” (Ex. 1–182–7). In a related comment, ORC stated that many industrial applications typically have exposures only 2–3 times the acceptable exposure limit; therefore, “selecting a respirator with an APF of 10 may mean there is only a remote chance of overexposure to a contaminant due to fit/wear variability” (Ex. 1–182–10).

7. Other Concerns With Nicas’ Method

The commenters raised several other issues with Dr. Nicas’ methodology. For example, 3M (Ex. 1–182–5) and CMA (Ex. 1–182–7) believed that the relationship between outside concentration and WPF (*i.e.*, WPF increases with increasing Co) was poorly understood; therefore, a sophisticated analysis of the data is questionable. Other commenters noted errors in the equations of the proposed model (*e.g.*, Ex. 1–182–1) and with the distribution of the respirator penetration values (Ex. 1–182–1).

8. Miscellaneous Comments (*e.g.*, ANSI APFs)

In addition to responding to the Nicas report, a number of commenters supported using the APFs recommended in the ANSI Z88.2–1992 respiratory protection standard (Exs. 1–182–1, 1–182–2, 1–182–5, 1–182–7, 1–182–10). These commenters stated that the members of the ANSI Z88.2 committee were “respected industrial hygiene and respirator experts” (Ex. 1–182–5), that the ANSI Z88.2–1992 APFs were “the appropriate values” (Ex. 1–182–7), and that the ANSI APFs “have been through the ANSI peer review process” (Ex. 1–182–5). In advocating use of the ANSI APFs, none of the commenters described the process by which the ANSI Z88.2 committee derived its APFs, or identified the studies and other information on which that committee relied. Furthermore, several commenters (Exs. 1–182–7, 1–

182–5, 1–182–10, 1–182–6, 1–182–8) noted that the ANSI Z88.2–1992 standard does not explicitly account for several factors in assigning APF values to different respirator classes, or the use of a respirator in different situations, which they indicated were necessary considerations. Moreover, some commenters (Exs. 1–182–11, 1–182–12) recommended APFs that differ from those published by the ANSI Z88.2 Committee. Other commenters believed that it was OSHA’s responsibility to show that the commonly used ANSI Z88.2 1992 APFs were erroneous (Ex. 1–182–2), and that the Agency should not use SWPF studies to derive APFs (Ex. 1–182–5). Several participants at the hearing for the final Respiratory Protection Standard stated that OSHA should issue a second NPRM to address the development of APFs (Exs. 1–182–1, 1–182–5, 1–182–10).

After carefully considering Dr. Nicas’ model and the comments received in response to his report of the model, the Agency concluded that other possible approaches to deriving APFs should be investigated. Accordingly, the Agency identified and collected available data for this purpose. Of particular interest were data that OSHA could use to discriminate between the performance of different respirator classes. The Agency gathered information from both published and non-published papers and reports, and included WPF, SWPF, PPF, and EPF studies; Health Hazard Evaluations conducted by NIOSH; respirator performance data from manufacturers, such as SWPF data submitted to OSHA by Bullard (Ex. 3–8); and other material related to assessing respirator performance. This information is in Docket H049 as Exhibits 2, 3, and 4.

To assist in evaluating the data, OSHA employed Dr. Kenneth Brown (a statistician) and several respirator authorities: Mr. Harry Ettinger, Dr. Gerry Wood of LANL, and Drs. James Johnson, Kenneth Foote, and Arthur Bierman of LLNL. After the Agency reviewed all of the studies and information, it decided to attempt to analyze only WPF and SWPF studies since they address respirator performance exclusively. OSHA discusses the work and findings of these individuals below.

B. Analyses of WPF Studies

OSHA contracted with Dr. Brown to investigate possible approaches, other than those approaches proposed by Nicas, to evaluate respirator performance data from WPF studies. The following discussion is a general description of the analyses performed by Brown, as well as his overall