

The Agency also developed the proposed provisions to be feasible and cost effective, and is specifying them in terms of objective criteria and the level of performance desired. In this regard, section VI ("Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis") of this preamble provides the benefits and costs of this proposal, and describes several other alternatives as required by section 205 of the UMRA (2 U.S.C. 1535). Based on this information, OSHA preliminarily concludes that the proposed APF and MUC provisions constitute the most cost-effective alternative for meeting its statutory objective of reducing risk of adverse health effects to the extent feasible.

### III. Events Leading to the Proposed Standard

#### A. Regulatory History

Congress created the Occupational Safety and Health Administration (OSHA) in 1970, and gave it the responsibility for promulgating standards to protect the health and safety of American workers. As directed by the OSH Act, the Agency adopted existing Federal standards and national consensus standards developed by various organizations such as the American Conference of Governmental Industrial Hygienists (ACGIH), the National Fire Protection Association (NFPA), and the American National Standards Institute (ANSI). The ANSI standard Z88.2-1969, "Practices for Respiratory Protection," was the basis of the first six sections (permissible practice, minimal respirator program, selection of respirators, air quality, use, maintenance and care) of OSHA's Respiratory Protection Standard (29 CFR 1910.134) adopted in 1971. The seventh section was a direct, complete incorporation of ANSI Standard K13.1-1969, "Identification of Gas Mask Canisters."

The Agency promulgated an initial Respiratory Protection Standard for the construction industry (29 CFR 1926.103) in April 1971. On February 9, 1979, OSHA formally applied 29 CFR 1910.134 to the construction industry (44 FR 8577). Agencies that preceded OSHA developed the original maritime respiratory protection standards in the 1960s (e.g., section 41 of the Longshore and Harbor Worker Compensation Act). The section designations adopted by OSHA for these standards, and their original promulgation dates, are: Shipyards—29 CFR 1915.82, February 20, 1960 (25 FR 1543); Marine Terminals—29 CFR 1917.82, March 27, 1964 (29 FR 4052); and Longshoring—

29 CFR 1918.102, February 20, 1960 (25 FR 1565). OSHA incorporated 29 CFR 1910.134 by reference into its Marine Terminal standards (Part 1917) on July 5, 1983 (48 FR 30909). The Agency updated and strengthened its Longshoring and Marine Terminal standards in 1996 and 2000, and these standards now incorporate 29 CFR 1910.134 by reference.

Under the Respiratory Protection Standard that OSHA initially adopted, employers needed to follow the guidance of the Z88.2-1969 ANSI standard to ensure proper selection of respirators. Subsequently, OSHA published an Advance Notice of Proposed Rulemaking ("ANPR") to revise the Respiratory Protection Standard on May 14, 1982 (47 FR 20803). Part of the impetus for this notice was the Agency's inclusion of new respirator requirements in the comprehensive substance-specific standards promulgated under Section (6)(b) of the OSH Act, e.g., fit testing protocols, respirator selection tables, use of PAPRs, changing filter elements whenever an employee detected an increase in breathing resistance, and requirements referring employees with breathing difficulties to a physician trained in pulmonary medicine, either at fit testing or during routine respirator use [see, e.g., 29 CFR 1910.1025 (OSHA's Lead Standard)]. The respirator provisions in these substance-specific standards took into account advances in respirator technology and changes in related guidance documents that were state-of-the-art when OSHA published these substance specific standards and, in particular, recognized that effective respirator use depends on a comprehensive respiratory protection program that includes use of APFs.

OSHA's 1982 ANPR sought information on the effectiveness of its current Respiratory Protection Standard, the need to revise this standard, and suggestions on the nature of the revisions. The 1982 ANPR referenced the ANSI Z88.2-1980 standard on respiratory protection with its table of protection factors, the 1976 report by Dr. Ed Hyatt from the LASL titled "Respiratory Protection Factors" (Ex. 2), and the RDL developed jointly by OSHA and NIOSH, as revised in 1978 (Ex. 9, Docket No. H049). Questions #2, #3, and #4 in the 1982 ANPR asked for comments on how OSHA should use protection factors. The Agency received responses from 81 interested parties. The commenters generally supported revising OSHA's Respiratory Protection Standard, and provided recommendations regarding approaches

for including a table of protection factors (Ex. 15).

On September 17, 1985, OSHA announced the availability of a preliminary draft of the proposed Respiratory Protection Standard. This preproposal draft standard included the public comments received in response to 1982 ANPR, and OSHA's own analysis of revisions needed in the Respiratory Protection Standard to account for state-of-the-art respiratory protection. The Agency received 56 responses from interested parties (Ex. 36) which OSHA carefully reviewed in developing the proposal.

On November 15, 1994, OSHA published the proposed rule to revise 29 CFR 1910.134, and provided public notice of an informal public hearing on the proposal (59 FR 58884). The Agency convened the informal public hearing on June 6, 1995. On June 15, 1995, as part of the public hearing, OSHA held a one-day panel discussion by respirator experts of APFs. Areas discussed included difficulties in measuring performance of respiratory protection in WPF and SWPF studies, statistical uncertainties regarding the distribution of data from these studies, and the problems associated with setting APFs for all respirators that protect all potential respirator users across a wide variety of workplaces and exposure conditions.

OSHA reopened the rulemaking record for the revised Respiratory Protection Standard on November 7, 1995 (60 FR 56127), requesting comments on a study performed for OSHA by Dr. Mark Nicas titled "The Analysis of Workplace Protection Factor Data and Derivation of Assigned Protection Factors" (Ex. 1-156). That study, which the Agency placed in the rulemaking docket on September 20, 1995, addressed the use of statistical modeling for determining respirator APFs. OSHA received 12 comments on the Nicas report. This report, and the comments received in response to it, convinced OSHA that more information would be necessary before it could resolve the complex issues regarding how to establish APFs, including what methodology to use in analyzing existing protection factor studies (see Section IV below for a more detailed explanation of the Nicas report and the comments made on it).

OSHA published the final, revised Respiratory Protection Standard, 29 CFR 1910.134, on January 8, 1998 (63 FR 1152). The standard contains worksite-specific requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator