

BILLING CODE 4510-26-C

VII. Summary and Explanation of the Proposed Standard

This section of the preamble provides a summary and explanation of each proposed revision to OSHA's Respiratory Protection Standard involving assigned protection factors.

A. Revisions to the Respiratory Protection Standard

This section addresses the revisions proposed for paragraphs (b), (d)(3)(i)(A), (d)(3)(i)(B), and (n) of OSHA's existing Respiratory Protection Standard at 29 CFR 1910.134.

Paragraph (b)—Definitions

Revisions to this paragraph would add two important definitions—"assigned protection factor" and "maximum use concentration"—to OSHA's Respiratory Protection Standard. The following sections explain these proposed definitions in detail.

1. Assigned Protection Factor

As part of its 1994 proposed rulemaking for the Respiratory Protection Standard, OSHA proposed a definition for assigned protection factors (APFs) that read as follows: "[T]he number assigned by NIOSH [the National Institute for Occupational Safety and Health] to indicate the capability of a respirator to afford a certain degree of protection in terms of fit and filter/cartridge penetration" (59 FR 58938). OSHA proposed this definition on the assumption that NIOSH would develop APFs for the various respirator classes, building on the APFs in the 1987 NIOSH Respirator Decision Logic (RDL) (59 FR 58901-58903). However, NIOSH subsequently decided not to publish a list of APFs as part of its 42 CFR part 84 Respirator Certification Standards (60 FR 30338), and reserved APFs for a future NIOSH rulemaking.

During his opening statement on June 15, 1995 at an OSHA-sponsored expert-panel discussion on APFs, Dr. Adam Finkel, then Director of the Agency's Directorate of Health Standards Programs, noted that OSHA would explore developing its own list of APFs (H-049, Ex. 707-X). The Agency then announced in the preamble to the final Respiratory Protection Standard (63 FR 1182) that it would propose an APF table "based on a thorough review and analysis of all relevant evidence" in a subsequent rulemaking. In the final Respiratory Protection Standard, OSHA reserved a table for APFs, a paragraph

[(d)(3)(i)(A)] for APF requirements, and a definition of APF under paragraph (b).

In its 1987 RDL, NIOSH defined APF as "[t]he minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users" (Ex. 1-54-437Q). The American National Standards Institute (ANSI) developed a definition for APF in its Z88.2-1992 Respiratory Protection Standard that reads, "The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators to properly fitted and trained users" (Ex. 1-50). The ANSI Z88.2 Subcommittee that developed the 1992 standard used the NIOSH definition of APF as a template for its APF definition; however, the Z88.2 Subcommittee revised the phrase "minimum anticipated protection" in the NIOSH definition to "expected workplace level of respiratory protection." It also dropped the NIOSH phrase "to a given percentage" from its definition.

The phrase "a given percentage" implies that some respirator users will not achieve the full APF under workplace conditions. The "given percentage" usually is about five percent, which is a percentage derived from statistical analyses of workplace protection factor (WPF) studies. In this regard, five percent represents the fifth percentile of the geometric distribution of protection factors for individual participants in a WPF study. Each participant's protection factor is the concentration of challenge agent outside the respirator (C_o) divided by the concentration of that agent inside the participant's respirator (C_i), or C_o/C_i ; therefore, the fifth percentile is the threshold for specifying the APF for the respirator tested under those workplace conditions. Using the fifth percentile means that about five percent of the employees who use the respirator under these workplace conditions may not achieve the level of protection assigned to the respirator (or class of respirators). Most WPF studies adopt the fifth-percentile threshold as the conventional standard, recognizing that about five percent of respirator users will not attain the APF determined for the respirator or class of respirators even when they receive proper fit testing and use the respirator correctly as part of a comprehensive respiratory protection program. However, ANSI dropped the phrase "to a given percentage" to reduce confusion (*i.e.*, the phrase did not specify a percentage), and to emphasize the level of protection needed by the

vast majority of employees who use respirators in the workplace.

The Agency's review of the available data on respirator performance, as well as findings from the personal protective equipment surveys (Exs. 6-1, 6-2), indicate that the existing definitions of APF are confusing to the respirator-using public. Accordingly, OSHA believes that the proposed definition would reduce confusion among employers and employees regarding APFs, thereby assisting employers in providing their employees with effective respirator protection consistent with its Respiratory Protection Standard.

The Agency revised the terms in the ANSI APF definition to improve clarity. OSHA's proposed definition for APF reads as follows:

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134.

The revisions made to the ANSI APF definition in developing this proposed APF definition include adding the phrase "when the employer implements a continuing, effective respiratory protection program as specified by 29 CFR 1910.134." The Agency added this phrase to emphasize the requirement that employers must select a respirator in the context of a comprehensive respiratory protection program. Accordingly, the APFs in Table I of this proposal do not apply when any of the program elements required by OSHA's Respiratory Protection Standard are absent from an employer's respirator program, including fit testing, maintenance, selection, use, training, and other specified elements. This wording is necessary because the level of employee protection afforded by the proposed APFs depends on the other elements of a comprehensive respiratory protection program being in place continuously, and operating effectively. Employers and employees cannot expect to achieve an APF reliably unless employers ensure that their employees use respirators in accordance with a continuing, effective respiratory protection program.

The proposed APF definition is an important addition to the Respiratory Protection Standard because it informs employers how the APF constrains respirator use. The APF can only be achieved by a respirator or class of respirators that are functioning properly in accordance with paragraphs (b) and (j) of the Respiratory Protection Standard. This means that the respirator must be capable of performing its