

**Mark E. Matthews,**  
Deputy Commissioner for Services and Enforcement.

Approved: July 21, 2004.

**Gregory F. Jenner,**  
Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 04-17539 Filed 8-3-04; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1910

[Docket No. H-049D]

RIN 1218-AC05

#### Controlled Negative Pressure REDON Fit Testing Protocol

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Final rule.

**SUMMARY:** In this rulemaking, OSHA is approving an additional quantitative fit testing protocol, the controlled negative pressure (CNP) REDON fit testing protocol, for inclusion in Appendix A of its Respiratory Protection Standard. The protocol affects, in addition to general industry, OSHA respiratory protection standards for shipyard employment and construction. The Agency is adopting this protocol under the provisions contained in the Respiratory Protection Standard that allow individuals to submit evidence for including additional fit testing protocols in this standard.

The CNP REDON protocol requires the performance of three different test exercises followed by two redonnings of the respirator, while the CNP protocol approved previously by OSHA specifies eight test exercises, including one redonning of the respirator. In addition to amending the Standard to include the CNP REDON protocol, this rulemaking makes several editorial and non-substantive technical revisions to the Standard associated with the CNP REDON protocol and the previously approved CNP protocol.

**DATES:** The final rule becomes effective September 3, 2004.

**ADDRESSES:** In compliance with 28 U.S.C. 2212(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, as

the recipient of petitions for review of this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** For technical inquiries, contact Mr. John E. Steelnack, Directorate of Standards and Guidance, Room N-3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210; telephone (202) 693-2289 or by facsimile (202) 693-1678. Copies of this **Federal Register** notice are available from the OSHA Office of Publications, Room N-3101, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington DC 20210; telephone (202) 693-1888. For an electronic copy of this notice, go to OSHA's Web site (<http://www.osha.gov>), and select "Federal Register," "Date of Publication," and then "2004."

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Respiratory Protection Standard includes the following three quantitative fit testing protocols: Generated-aerosol; ambient-aerosol condensation nuclei counter; and controlled negative pressure (CNP). Part II of Appendix A of the Respiratory Protection Standard specifies, in part, the procedure individuals must follow to submit new fit testing protocols for the Agency's consideration. The criteria OSHA uses for determining whether to propose adding a fit testing protocol to the Respiratory Protection Standard include: (1) A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory tested the protocol and found it to be accurate and reliable; or (2) an article published in a peer-reviewed industrial-hygiene journal describing the protocol, and explaining how test data support the accuracy and reliability of the protocol. When a protocol meets one of these criteria, the Agency conducts a notice-and-comment rulemaking under Section 6(b)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655). As OSHA noted in the proposal, the CNP REDON protocol met the second of these criteria (68 FR 33887; June 6, 2003).

##### II. Summary and Explanation of the Final Standard

###### A. Introduction

With his letter submitting the CNP REDON protocol for review, Dr. Clifton D. Crutchfield included copies of two peer-reviewed articles from industrial-hygiene journals describing the

accuracy and reliability of the proposed protocol (Exs. 2 and 3). In this submission, Dr. Crutchfield also described in detail the equipment and procedures required to administer the proposed protocol. According to this description, the proposed protocol is a variation of the CNP protocol developed by Dr. Crutchfield in the early 1990s, and which OSHA approved for inclusion in paragraphs (a) and (d) of Part I.C.4 of Appendix A when the Agency revised its Respiratory Protection Standard (63 FR 1152; January 8, 1998). Although the proposed protocol has the same fit-test requirements and uses the same test equipment as the CNP protocol previously approved by OSHA, it includes only three test exercises followed by two redonnings of the respirator instead of the eight test exercises and one respirator redonning required by the previously approved CNP protocol. The three test exercises, listed in order of administration, are normal breathing, bending over, and head shaking. The procedures for administering these three test exercises and the two respirator donnings to an employee, and for measuring respirator leakage during each test, are described below:

- Facing forward. In a normal standing position, without talking, the test subject must breathe normally for 30 seconds; then, while facing forward, he or she must hold his or her breath for 10 seconds for test measurement.
- Bending over. The test subject (i.e., employee) must bend at the waist for 30 seconds as if he or she is going to touch his or her toes; then, while facing parallel to the floor, he or she must hold his or her breath for 10 seconds for test measurement.
- Head shaking. The test subject must shake his or her head back and forth vigorously several times while shouting for approximately three seconds; then, while facing forward, he or she must hold his or her breath for 10 seconds for test measurement.
- First redonning (REDON-1). The test subject must remove the respirator, loosen all facepiece straps, and then redon the respirator mask; after redonning the mask, he or she must face forward and hold his or her breath for 10 seconds for test measurement.

- Second redonning (REDON-2). The test subject must remove the respirator, loosen all facepiece straps, and then redon the respirator mask again; after redonning the mask, he or she must face forward and hold his or her breath for 10 seconds for test measurement. As noted earlier, Dr. Crutchfield submitted two peer-reviewed journal articles that

provided information on the accuracy and reliability of the proposed CNP REDON protocol. In the first of these articles, the most important conclusion made by the authors was that the protocol results in substantially lower respirator fit factors overall than the most commonly used ambient-aerosol protocol. Lower fit factors indicate that the CNP REDON protocol detects more respirator leaks than the ambient-aerosol protocol, thereby providing employees with an increased margin of safety when they select respirators. The main conclusion reached by the authors in the second article was that the overall fit factors obtained from the three exercises and two redonings required by the CNP REDON protocol are the same as the overall fit factors found when using the previously approved CNP protocol described in the Respiratory Protection Standard. Therefore, compared to the previously approved CNP protocol, the CNP REDON protocol submitted by Dr. Crutchfield obtains at least the same overall fit factors with fewer exercises and in less time.

OSHA found that the information submitted by Dr. Crutchfield in support of the CNP REDON protocol met the criteria for proposing to add new fit testing protocols to Part I of Appendix A of the Respiratory Protection Standard. Therefore, the Agency initiated a rulemaking proposing to approve the CNP REDON protocol for inclusion in Appendix A of the Respiratory Protection Standard. However, because the only difference between the proposed CNP REDON protocol and the previously approved CNP protocol is the exercise procedure used during fit testing, the Agency proposed to limit the regulatory text revisions to a description of the proposed CNP REDON exercise procedure, and to refer instead to the previously approved CNP protocol described in paragraphs (a) and (c) of Part I.C.4 for information on CNP fit testing requirements and the CNP test instrument.

#### B. Editorial and Technical Revisions to the Respiratory Protection Standard

In the proposal, OSHA also included several editorial and technical revisions to the language describing the two CNP fit testing protocols. The first proposed editorial revision added the CNP REDON protocol to the exception already specified for the previously approved CNP protocol under paragraph 14(a) of Part I.A in Appendix A of the Respiratory Protection Standard. Accordingly, paragraph 14(a) would exempt both the previously approved

CNP protocol, as well as the proposed CNP REDON protocol, from the test exercises specified for the other approved fit testing protocols listed in the appendix. OSHA believed that this revision is necessary because the CNP REDON protocol consists of a test exercise procedure that differs substantially from the procedure required for the other OSHA-approved fit testing protocols.

The second editorial revision included in the proposal involved the introductory paragraph describing the previously approved CNP protocol in Part I.C.4 of Appendix A of the Respiratory Protection Standard. The eighth sentence in this paragraph refers to the CNP instrument manufacturer as "Dynatech Nevada." However, the instrument manufacturer now is Occupational Health Dynamics of Birmingham, Alabama. OSHA proposed to revise this sentence to identify the current manufacturer of this instrument.

As noted in the proposal, Dr. Crutchfield stated that test administrators use either an auditory warning device or the screen tracing currently provided on the CNP test instrument to detect participants' failure to hold their breath for the required 10-second period when measuring respirator fit (Ex. 14). While using the screen tracing for this purpose was not part of the previously approved CNP protocol, the Agency believed that such a visual warning device would be a useful adjunct in measuring respirator fit under both the previously approved CNP protocol and the proposed CNP REDON protocol. Therefore, the Agency proposed to revise paragraph (c) of the previously approved CNP protocol (under Part I.A.4 of the Respiratory Protection Standard) to include the screen tracing currently provided on the CNP test instrument as a visual warning device to detect test subjects' non-compliance with the breath-hold procedure.

In a 1998 journal article entitled "CNP Fit Testing Under OSHA's Updated Respiratory Protection Standard," published in *Respiratory Protection Update*, Dr. Crutchfield indicated that the Agency's description of the CNP fit-test requirements in paragraph (a)(5) of the previously approved CNP protocol contained an error (Ex. 8). Specifically, he noted the breath-hold requirement in paragraph (a)(5) should be 10 (not 20) seconds. OSHA agreed. Accordingly, the Agency proposed to revise this requirement because implementing correct fit-test procedures would improve the assessment of respirator fit factors using the previously approved

CNP protocol, as well as the proposed CNP REDON protocol.

#### C. Comments to the Proposal

In the proposal, OSHA requested the public to submit comments and data regarding the accuracy and reliability of the CNP REDON protocol, as well as its effectiveness in detecting respirator leakage and its usefulness in selecting respirators that protect employees from airborne contaminants in the workplace (68 FR 33887; June 6, 2003).

Specifically, the Agency invited public comment on the following issues:

- Were the studies described in the peer-reviewed articles well controlled, and conducted according to accepted experimental design practices and principles?
- Were the results of the studies described in the peer-reviewed articles properly, fully, and fairly presented and interpreted?
- Will the proposed protocol reliably identify respirators with unacceptable fit as effectively as the quantitative fit testing protocols already listed in Part I.C of Appendix A of the Respiratory Protection Standard?
- Will the proposed protocol generate reproducible fit testing results?
- Should OSHA expand application of the proposed protocol fit-test exercises to other quantitative fit tests (e.g., ambient aerosol tests)?
- Will the proposed editorial and technical revisions to Part I of Appendix A improve proper implementation of the approved CNP protocol and the proposed CNP REDON protocol?

The Agency received 66 written comments and 116 electronic comments in response to its request for comments in the proposal (Exs. 3-1 to 3-66 and 4-1 to 4-116, respectively). The following paragraphs in this section address the comments made on each of the six issues described previously.

#### 1. Were the Studies Described in the Peer-Reviewed Articles Well Controlled, and Conducted According to Accepted Experimental Design Practices and Principles?

Dr. Kent Oestenstad of the University of Alabama at Birmingham emphasized the high quality of the research studies supporting the CNP REDON protocol. In doing so, he stated that the research studies "were well controlled and conducted according to established and accepted experimental design" (Ex. 4-88), a judgment confirmed by their acceptance for publication in peer-reviewed journals.

Several commenters questioned the research underlying the proposed protocol. One commenter stated that it

was inappropriate to validate the protocol based on ambient-aerosol concentrations measured using PortaCount equipment (Ex. 4-102). Another commenter asserted that the underlying research studies did not adequately support the accuracy and reliability of the proposed protocol, and cited problems with each of the articles (Ex. 3-32). In his view, the first article was deficient because only three test exercises (and no redonning exercises) from the proposed protocol were used, poor-fitting masks were not included, the numbers of test subjects were statistically inadequate, data from half-mask and full-facepiece respirators were mixed inappropriately, a mixture of fit factors for the minimum pass-fail criterion was used, data from two different ambient-aerosol protocols were combined, paired t-tests were not used when comparing each test subject's performance on the two protocols, and statistical sensitivity was poor (see, also, Exs. 3-60 and 4-84). The same commenter found the second article inadequate in that poor-fitting masks were not included and the criteria for evaluating new fit-test protocols specified in ANSI Z88.10-2001 were not met. Two commenters claimed that the proposed protocol cannot be evaluated using pass-fail fit factors derived using an aerosol challenge agent because a low correlation exists between fit factors assessed using the previously approved CNP protocol and an aerosol-based protocol (Exs. 4-92 and 4-102).

Regarding these comments, a review of the first study shows that redonning was performed between each of the fit tests, while the second study used the full CNP REDON protocol, including two redonning exercises. In addition, the pass-fail distributions for the studies indicate that respirator fit varied substantially among the test subjects. While the Agency agrees that inaccurate and unreliable measurements and combining results for different respirator types may lead to inconsistent results with large statistical variations, the peer-reviewed studies showed that the results were consistent and that large statistical variations did not occur. For example, these studies showed clearly that fit factors from the CNP REDON protocol were consistently lower than fit factors from the ambient-aerosol protocol and the CNP protocol previously approved by OSHA. Additionally, to be accepted for publication in peer-reviewed journals, the studies had to conform with the experimental-design and statistical procedures and practices used by the

industrial-hygiene research community to collect and analyze data.

As for the observation that the studies used an insufficient number of test subjects, the industrial-hygiene research community does not use a specified number of test subjects to assess fit testing protocols. Moreover, specifying a minimum number of test subjects for fit testing research would be arbitrary. Finally, had the sample sizes been too small to produce reliable results, the studies would not have been accepted for publication in peer-reviewed journals.

The commenters who addressed fit factors based on aerosol challenge agents provided no data or additional information to support their position and, thus, were not able to negate the results of the first study submitted by Dr. Crutchfield, which showed a close correspondence between the results of the CNP REDON and ambient-aerosol protocols.

In summary, the Agency finds that these comments did not identify any shortcoming in the research underlying the proposed protocol that would offset the criteria used to evaluate that research under the peer-review process. Furthermore, OSHA considers the results described in these articles to be reliable and valid. Therefore, the Agency has concluded that these results provide robust scientific support for the CNP REDON protocol as described in the proposal.

## 2. Were the Results of the Studies Described in the Peer-Reviewed Articles Properly, Fully, and Fairly Presented and Interpreted?

Dr. Oestenstad observed that “[s]tatements in the conclusions and results were fairly reported and interpreted” (Ex. 4-88). However, another commenter observed that “virtually all studies showing favorable performance by the CNP method were authored or co-authored by the inventor/developer of that method,” an observation made by other commenters as well (Exs. 3-32, 3-58, 4-84, and 4-91).

The Agency finds Dr. Oestenstad's comments convincing because, as noted in his responses to the third issue (see below), his laboratory has performed independent research on the CNP protocol previously approved by OSHA. Therefore, Dr. Oestenstad is in an ideal position to know whether the results of the peer-reviewed articles were properly, fully, and fairly presented and interpreted, and whether the CNP protocol provides equivalent protection to workers. Additionally, the peer-review process specifically removes

effects that may have been due to bias on the part of the authors.<sup>1</sup> The Agency finds that the observations made by the other commenters simply oppose the supporting studies without presenting information or data that contradict the results.

## 3. Will the Proposed Protocol Reliably Identify Respirators With Unacceptable Fit as Effectively as the Quantitative Fit Testing Protocols Already Listed in Part I.C of Appendix A of the Respiratory Protection Standard?

In his comments, Dr. Crutchfield described the two peer-reviewed studies that he submitted to OSHA in support of the proposed CNP REDON protocol, and stated that these studies showed that fit factors obtained using this protocol were significantly lower than fit factors obtained using the ambient-aerosol fit test previously approved by OSHA (Ex 4-13). He noted that the first study assessed the impact of fit-test exercises and donning on respirator fit; consequently, he questioned the current practice of basing determinations of respirator fit on a single donning of a respirator mask.<sup>2</sup> The second study involved fit testing Tucson firefighters using both the previously approved CNP protocol and the proposed CNP REDON protocol. Dr. Crutchfield observed that this study demonstrated that fit factors obtained using the proposed protocol were lower than fit factors achieved with the previously approved CNP protocol, although this difference was not significant statistically.

Dr. Crutchfield also submitted, with his comments, a paper that he drafted (Ex. 4-13-1). This paper described two studies in which a hypodermic needle was used to allow air to leak into the facepiece of a respirator in a predictable manner (*i.e.*, to simulate poor respirator fit). The first study measured this leakage in half-mask respirators worn by five test subjects who each performed six fit-test exercises while being assessed using either the FitTester 3000 or the PortaCount Plus.<sup>3</sup> The second

<sup>1</sup> To ensure minimal bias on the part of both authors and peer reviewers, the journal *Applied Occupational and Environmental Hygiene* (the journal in which Dr. Crutchfield published the first article submitted in support of the CNP REDON protocol) requires a double-blind review (*i.e.*, both the authors and the reviewers remain anonymous to each other).

<sup>2</sup> In the first study, multiple donnings consisted of removing and redonning the respirator between each fit test.

<sup>3</sup> The exercises used for the CNP protocol were facing forward, moving the head left, moving the head right, moving the head up, moving the head down, and facing forward, while the six exercises used for the ambient-aerosol protocol were normal breathing, deep breathing, moving the head side to

study evaluated this leakage at three locations in a half-mask or full-facepiece respirator mounted on a head form; this study also used the FitTester 3000 and the PortaCount Plus to assess the leakage. The results of these two studies showed that the CNP fit testing system produced substantially less variability, and detected more respirator leakage, than the ambient-aerosol fit testing system.

This paper also described a meta-analysis of six published studies, each of which compared fit factors obtained for the CNP and ambient-aerosol fit-test systems. Consistent with the results of the previous two studies, the meta-analysis found that the CNP fit tests produced consistently and substantially lower fit factors than the ambient-aerosol fit tests.

OSHA believes the three studies described in Dr. Crutchfield's unpublished paper deserve serious consideration. The first two studies warrant consideration because the hypodermic-needle methodology has been demonstrated to be a reliable and valid measure of respirator leakage in at least two peer-reviewed journals,<sup>4</sup> and the methodology also is described in Annex A2 of the ANSI Z88.10-2001 consensus standard as a research methodology for use in validating fit testing protocols. The third study did not involve collecting independent data, but used meta-analysis for the purpose of determining the overall strength of the protocol differences obtained in studies already published in peer-reviewed journals. The Agency also notes that while it is possible that differences between the exercises used in the CNP and ambient-aerosol protocols in the first study may account for some of the differences observed between the protocols, it is clear that the direction of these differences (*i.e.*, the CNP protocol being more conservative than the ambient-aerosol protocol) is consistent with the findings of the second and third studies, as well as the peer-reviewed articles submitted by Dr. Crutchfield in support of the proposed CNP REDON protocol.

Dr. Oestenstad noted that, in the second peer-reviewed study submitted by Dr. Crutchfield in support of the proposed protocol, “[t]he distributions

side, moving the head up and down, reciting the Rainbow Passage, and normal breathing.

<sup>4</sup> Crutchfield, C. D., Park, D. L., Henshel, J. L., *et al.* (1995). Determinations of known respirator leakage using controlled negative pressure and ambient aerosol QNFT systems. *American Industrial Hygiene Association Journal*, vol. 56, pp. 16-23; and Crutchfield, C. D. and Park, D. L. (1997). Effect of leak location on measured respirator fit. *American Industrial Hygiene Association Journal*, vol. 58, pp. 413-417.

of fit factors [measured] by the two methods were shown to be almost identical, and fit factors [measured] by the [proposed CNP REDON protocol] were lower than those [measured] by the [previously approved CNP protocol] at low levels of fit” (Ex. 4-88). He stated further that “[s]tudies by my students have found that the negative pressure method produced a significantly lower geometric standard deviation than the aerosol method for a series of fit tests on the same subjects wearing the same mask.”

OSHA finds that Drs. Crutchfield and Oestenstad have demonstrated the reliability and effectiveness of the CNP REDON protocol in detecting respirator leaks, and that this and similar CNP protocols consistently produce fit factors that are substantially lower than fit factors obtained using the ambient-aerosol fit testing protocol. The Agency considers their comments especially significant because they are based on data collected under controlled laboratory conditions.

Several commenters who currently use the previously approved CNP protocol endorsed the proposed protocol because they believed it would increase the effectiveness of the fit testing by improving the ability of employees to detect leaks while donning and doffing a respirator, enhancing confidence among employees and employers that the respirators fit properly, and yielding fit factors that do not differ substantially from fit factors obtained using the previously approved CNP protocol (Exs. 3-5, 3-7, 3-25, and 3-46). One commenter, who used the PortaCount protocol, disagreed with these comments, claiming that both CNP fit testing protocols would diminish effectiveness by interfering with training employees in the capabilities and limitations of their respirators (Ex. 4-84). However, this commenter did not elaborate on the supposed interference, provide any data, or present evidence of experience in administering either of the CNP protocols. One commenter believed that existing quantitative fit tests would detect respirator leakage more effectively than the proposed protocol (Ex. 4-99). However, this commenter provided no evidence on which to base this claim, which the Agency finds to be unsupported by other evidence in the record, including the peer-reviewed studies submitted by Dr. Crutchfield.

The remaining comments lend strong support to the proposed CNP REDON protocol in that they generally found that the proposed protocol would assess respirator fit effectively, and also would train employees to detect leakage while

donning and doffing a respirator (Exs. 3-5, 3-7, 3-25, and 3-46). The Agency agrees that the CNP REDON protocol, through effective fit testing and training, also will improve employee confidence that their respirators fit properly.

Several commenters asserted that the redonning exercises were not valid (Exs. 3-32, 4-6, and 4-66). Two commenters took issue with the elimination of the head side-to-side, head up-and-down, and talking exercises from the proposed protocol, which the first of these commenters asserted had a history of exposing poor respirator fit (Exs. 3-32 and 3-61). One commenter questioned the validity of the head-shake exercise, while another commenter stated that the two articles submitted in support of the proposed protocol failed to demonstrate that the head-shake or multiple-donning exercises would expose the same leaks as the head-movement exercises (Exs. 3-60 and 3-32). This second commenter stated further that the first peer-reviewed article submitted by Dr. Crutchfield in support of the proposed protocol showed that “the talking exercise produces consistently lower fit factors than other exercises for fit test methods [e.g., the ambient-aerosol and generated-aerosol protocols],” but noted this exercise was impossible to perform under the proposed or previously approved CNP protocols (Ex. 3-32). Two commenters questioned the validity of the breath-hold requirement (Exs. 3-28 and 3-61).

OSHA notes that none of the criticisms addressing specific test exercises were substantiated by any data or other evidence. Additionally, these comments did not take into consideration the evidence in the record showing that the proposed protocol, even after eliminating these test exercises, still yields reliable and accurate fit factors that are consistently below (*i.e.*, more conservative than) the fit factors obtained using the ambient-aerosol protocol. The comments regarding the validity of the redonning exercises ignore the important contribution these exercises make in detecting respirator leaks, as described in the results of the second peer-reviewed study submitted by Dr. Crutchfield. One of these commenters, despite criticizing the redonning exercise, stated elsewhere in his comments that he “has no disagreement with the concept of multiple mask donnings as part of a respirator fit test” (Ex. 3-32). Moreover, the breath-hold requirement has been validated in the studies described in Dr. Crutchfield's peer-reviewed articles, and is a fundamental part of both the proposed and previously approved CNP protocols

(i.e., test subjects must maintain negative pressure inside the respirator for the equipment to detect leakage during the various exercises).

In a general criticism of the proposed protocol, several commenters referred to a NIOSH study in which the previously approved CNP protocol (and, by implication, the proposed CNP REDON protocol) performed poorly when test subjects were exposed to Freon as a challenge agent during fit testing (Exs. 3-32, 3-45, 4-91, and 4-92).<sup>5</sup> However, in explaining the poor results obtained using the CNP protocol, NIOSH stated, “[T]he possibility of changes in fit during the Freon-113 exposure in the chamber may have placed the \* \* \* CNP method[s] at a disadvantage; any change in fit during the Freon-113 exposure would tend to decrease the observed correlation” (Ex. 3-32-1, p. 866).

#### 4. Will the Proposed Protocol Generate Reproducible Fit Testing Results?

OSHA received no comments on this issue, which suggests that reproducibility of the fit testing results was not a critical concern to the regulated community. In addition, the Agency believes that the consistency of results between the two peer-reviewed studies demonstrates that fit factors obtained using the CNP REDON protocol would be highly reproducible.

#### 5. Should OSHA Expand Application of the Proposed Protocol Fit-Test Exercises to Other Quantitative Fit Tests (e.g., Ambient Aerosol Tests)?

Dr. Oestenstad concluded that “no studies \* \* \* have validated the measurement of respirator leakage using the ambient aerosol method and the proposed exercise protocol,” and cautioned that “[a]pplication of the proposed exercise protocol to the ambient aerosol method would be scientifically inappropriate if no studies have been conducted” (Ex. 4-88). Another commenter, who opposed OSHA’s acceptance of the previously approved and proposed CNP protocols, also recommended that “OSHA \* \* \* accept all \* \* \* fit testing protocols [approved under ANSI Z88.10-2001] including those for generated aerosol and particle counting (ambient aerosol) methods” (Ex. 3-32). An additional 65 commenters endorsed the recommendation that OSHA should approve all of the protocols specified by this ANSI standard, including the abbreviated PortaCount ambient-aerosol protocol and the ANSI provision that

allows a 30-second exercise duration. Several commenters urged the Agency to reduce each of the exercises in the PortaCount ambient-aerosol protocol to 30 seconds, while other commenters asserted that such a reduction would have no adverse affect on fit factors obtained using the PortaCount ambient-aerosol protocol (Exs. 3-34, 3-37, 3-47, 4-18, 4-45, 4-47, 4-51, 4-53, 4-93, 4-101, and 4-112). Some commenters noted that the existing Canadian respirator fit testing standard (CSA Z94.4-02) permits 30-second fit testing exercises for the PortaCount ambient-aerosol protocol (Exs. 3-32, 3-62, 4-62, 4-72, and 4-114). Two commenters wanted to shorten the PortaCount ambient-aerosol protocol by removing the grimace exercise (Exs. 3-23 and 3-53).

The Agency concurs with Dr. Oestenstad’s conclusion that no studies are available demonstrating that the exercises developed for the proposed CNP REDON protocol would determine a valid fit factor if used in another quantitative fit testing protocol. No other commenter provided evidence to refute this conclusion. Regarding the remaining comments in the previous paragraph, the proposal did not address using ANSI Z88.10-2001 to justify adopting any fit testing protocol. In section IV.G of the proposal (“Applicability of Existing Consensus Standards”), OSHA referred to ANSI Z88.10-2001 for the purpose of comparing the proposed fit test to the CNP REDON protocol described in the ANSI standard; OSHA did not use this reference to substantiate the accuracy, reliability, or validity of the proposed protocol or any other fit testing protocol. The Agency uses only the criteria specified in Part II of Appendix A of the Respiratory Protection Standard to determine whether to propose a new fit testing protocol or to modify protocols previously approved by OSHA (e.g., reducing exercise times or eliminating an exercise). OSHA’s Respiratory Protection Standard is clear on the appropriate criteria and the method for assessing a new protocol. The Agency cannot consider any new fit testing protocol for approval that does not meet these criteria, regardless of its acceptance under ANSI Z88.10-2001 or any other standard (e.g., the Canadian respirator fit testing standard (CSA Z94.4-02)).

#### 6. Will the Proposed Editorial and Technical Revisions to Part I of Appendix A Improve Proper Implementation of the Approved CNP Protocol and the Proposed CNP REDON Protocol?

Two commenters questioned the efficacy of the two types of breath-hold warning devices (i.e., auditory or visual), noting that the test operator could continue repeating the same exercise until achieving a passing fit factor (Exs. 3-32 and 3-60). In addition, one of these commenters recommended clarifying the CNP REDON instructions to ensure that test subjects: do not adjust their respirator masks during fit testing (to increase test validity); remove their respirator masks completely before redonning them (to provide two distinct measurements); and perform a five-minute comfort-assessment period prior to beginning the exercises (Ex. 3-32). This commenter also noted that the proposal required calculating the harmonic mean of the fit testing results in determining a final fit factor for an employee’s respirator; the commenter stated, “There are very few people who know what a harmonic mean is. Please provide the exact equation” (Ex. 3-32). The commenter also asserted that the validity of the proposed protocol would be improved if employees had to pass both redonning exercises (i.e., so that high fit factors achieved on the other exercises would not offset poor fit factors obtained on the redonning exercises) (Ex. 3-32).

OSHA agrees with the observations made by the two commenters that continuing a fit-test exercise after activating the breath-hold warning device could invalidate the fit test, which may compromise proper respirator selection and employee protection. Accordingly, the Agency has added the phrase “and restarted from the beginning” to the paragraph describing the breath-hold warning devices. The Agency believes that requiring operators to repeat a failed fit test (as indicated by activation of the breath-hold warning device) from the beginning will enhance the validity of the fit test and increase the likelihood that employees will select the correct respirator.

In response to the comment that permitting employees to adjust respirators during fit testing can invalidate the results, the Agency is adding language to paragraph C.4(a)(6) of the CNP REDON protocol prohibiting respirator adjustments once the fit-test exercises begin. This language is consistent with the existing requirement in Appendix A Part I.A.14(b) for the

<sup>5</sup> Exs. 3-32-1 and 3-32-2 in the docket are copies of articles describing these NIOSH studies.

other fit testing protocols. OSHA concludes that this revision will increase the validity of fit testing results and the protection afforded to the employee by a properly fitting respirator.

OSHA also agrees with the recommendation to clarify the instructions so that test subjects perform two complete redonnings. The revised instructions now require test subjects to remove their respirator masks, loosen the straps, and then redon their respirators. The Agency believes that this revision will ensure that each redonning exercise contributes independently to the overall fit-test score, thereby enhancing proper respirator selection. However, OSHA is not including in the revised instructions a description of the five-minute comfort-assessment period because the general instructions for administering fit tests, including the CNP protocol, already require employers to implement a comfort-assessment period prior to fit testing.<sup>6</sup> Therefore, repeating these instructions under the section that describes the CNP protocols is redundant.

The Agency agrees with the commenter who recommended that delineating a specific method for calculating a harmonic mean would be useful in accurately calculating fit factors from the results of the CNP REDON protocol. OSHA believes that using such a method would save time in making these calculations and, additionally, would reduce errors in determining fit factors. While the commenter did not identify in his comments a procedure for calculating a harmonic mean, the Agency has selected for this purpose a method similar to the one described in the ANSI Z88.10–2001 standard. The ANSI calculation method is accepted generally by the industrial-hygiene community, and it also is the method required in Appendix A of OSHA's Respiratory Protection Standard for determining fit factors using the results of the ambient-aerosol protocol.

OSHA is not persuaded that test subjects need to pass both redonning exercises so that the contribution of these exercises would not be offset by the other exercises, including the head-shaking and bending-over exercises. As is true for all quantitative fit testing protocols including the CNP REDON protocol, it is the fit factor obtained by averaging all of the fit-test scores obtained during fit testing that is important in assessing respirator fit, not

the test score obtained from individual fit tests. OSHA currently does not impose a requirement that other quantitative fit tests listed in Appendix A of the Respiratory Protection Standard must have test subjects pass every fit testing exercise, and no evidence was submitted by the commenter to suggest that such a revision is necessary for the CNP REDON protocol.

#### D. Conclusions

After reviewing the comments submitted to the record, the Agency finds that the proposed CNP REDON protocol is supported by peer-reviewed studies that were well controlled, conducted according to accepted experimental design practices and principles, and that produced results that were properly, fully, and fairly presented and interpreted. In addition, based on the studies and the comments in the record, the Agency concludes that the proposed protocol will effectively and reliably identify respirators with unacceptable fit as well as other quantitative fit tests previously approved by OSHA, and also will generate reproducible fit testing results. Moreover, the proposed fit testing exercises are specific to the CNP REDON protocol, and no evidence is available in the rulemaking record to support applying the exercises to other quantitative fit tests previously approved by OSHA. The record also indicates that the editorial and technical revisions described in the proposal are appropriate. Additionally, the Agency adopted several other technical and editorial revisions recommended by commenters; OSHA believes these revisions will ensure proper selection of respirators for employee use.

### III. Procedural Determinations

#### A. Legal Considerations

OSHA's Respiratory Protection Standard is based on evidence that fit testing is necessary to ensure proper respirator fit for employees; proper respirator fit, in turn, protects employees against excessive exposure to airborne contaminants in the workplace. Employers covered by this revision already must comply with the fit testing requirements specified in paragraph (f) of OSHA's Respiratory Protection Standard at 29 CFR 1910.134. Accordingly, these fit testing provisions currently are protecting their employees from the significant risk that results from poorly fitting respirators. For this final standard, the Agency has determined that the new CNP REDON fit testing protocol provides employees with protection that is comparable to

the protection afforded to them by the existing fit testing provisions. In this regard, the CNP REDON protocol is not expected to replace existing fit testing protocols, but instead is an alternative to them. Therefore, OSHA finds that the final standard does not directly increase or decrease the protection afforded to employees, nor does it increase employers' compliance burdens.

#### B. Economic Analysis and Regulatory Flexibility Certification

The final standard is not a significant rulemaking under Executive Order 12866, or a "major rule" under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501) or Section 801 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 601). The final standard imposes no additional costs on any private or public sector entity, and does not meet any of the criteria for a significant or major rule specified by the Executive Order or relevant statutes.

The CNP REDON protocol offers employers an additional option to fit test their employees for respirator use. In addition to the CNP protocol previously approved by OSHA, which continues to be an option, the Agency is adding the CNP REDON protocol. According to a recent NIOSH–BLS survey of respirator use, approximately 25,000 of 282,000 establishments currently use the previously approved CNP protocol (see Ex. 6–3, Docket H–049C). With this final rule, employers now have a choice between the previously approved CNP protocol consisting of eight exercises, including one redonning of the respirator, or the new CNP REDON protocol, which involves three exercises and two redonnings of the respirator.

By providing regulatory flexibility to employers, the addition of the CNP REDON protocol may reduce their costs in terms of decreasing the time required to fit test their employees for respirator use. In this regard, OSHA assumes that some employers who now use the previously approved CNP protocol will adopt the CNP REDON protocol. A number of employers who are purchasing new or replacement equipment for administering fit tests also will select the CNP REDON protocol because it consists of fewer exercises than the previously approved CNP and ambient-aerosol protocols, thereby decreasing the time and cost required for them to fit test their employees. However, the Agency believes that the CNP REDON protocol approved under this rulemaking is unlikely to be adopted by employers who currently use the ambient-aerosol

<sup>6</sup> See Appendix A, Part I, A., paragraph 14(b) of the Respiratory Protection Standard.

protocols because these employers already have made an equipment and training investment to administer these fit testing protocols. Finally, OSHA has included the screen tracing in the previously approved CNP and CNP REDON protocols as a visual warning device to detect non-compliance by employees being fit tested with the breath-hold procedure required by these protocols. The Agency concludes that this tracing adds no cost burden to employers who use these protocols because, as noted earlier, the manufacturer already provides this capability on the CNP test equipment.

In summary, OSHA concludes that this rulemaking imposes no additional costs on employers. Accordingly, OSHA certifies that this rulemaking has no significant impact on a substantial number of small businesses. Therefore, the Agency has not prepared a Final Regulatory Flexibility Analysis.

#### C. Paperwork Reduction Act

After analyzing the fit testing provisions of this final rule in terms of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.* and 5 CFR part 1320), OSHA determined that these provisions do not add to the existing collection-of-information (*i.e.*, paperwork) requirements regarding fit testing employees for respirator use. The paperwork requirement specified in paragraph (m)(2) of the existing Respiratory Protection Standard at 29 CFR 1910.134 specifies that employers must document and maintain the following information on quantitative fit tests administered to employees: The name or identification of the employee tested; the type of fit test performed; the specific make, model, style, and size of respirator tested; the date of the test; and the strip chart recording or other recording of the test results. The employer must maintain this record until the next fit test is administered. However, this paperwork requirement remains the same whether employers use the other fit testing protocols already listed in Part I of Appendix A of the Respiratory Protection Standard, or implement the CNP REDON fit testing protocol instead. Therefore, use of the CNP REDON protocol in the context of the existing fit testing protocols does not require an additional paperwork-burden determination because OSHA already accounted for this burden during the final rulemaking for the Respiratory Protection Standard (see 63 FR 1152–1154; OMB Control Number 1218–0099).

OSHA solicited comments on this determination in the June 6, 2003 **Federal Register** (68 FR 33891). The

Agency did not receive any public comments questioning this determination. Therefore, OSHA concludes that the final rule does not add any burden hours to the existing collection-of-information requirements associated with fit testing for employees for respirator use.

#### D. Federalism

The Agency reviewed the final standard revision according to the most recent Executive Order on Federalism (Executive Order 13132, 64 FR 43225, August 10, 1999). This Executive Order requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. The Executive Order allows Federal agencies to preempt state law only with the expressed consent of Congress. In such cases, Federal agencies must limit preemption of state law to the extent possible.

Under section 18 of the Occupational Safety and Health Act of 1970 (OSH Act), Congress expressly provides OSHA with authority to preempt state occupational safety and health standards to the extent that the Agency promulgates a Federal standard under section 6 of the OSH Act. Accordingly, section 18 of the OSH Act authorizes the Agency to preempt state promulgation and enforcement of requirements dealing with occupational safety and health issues covered by OSHA standards unless the state has an OSHA-approved occupational safety and health plan (*i.e.*, is a State-plan State). (See *Gade v. National Solid Wastes Management Association*, 112 S. Ct. 2374 (1992).) Therefore, with respect to states that do not have OSHA-approved plans, the Agency concludes that this revision conforms to the preemption provisions of the OSH Act. Additionally, section 18 of the OSH Act prohibits states without approved plans from issuing citations for violations of OSHA standards; the Agency finds that the final rulemaking does not expand this limitation.

OSHA has authority under Executive Order 13132 to add the CNP REDON fit testing protocol to its Respiratory Protection Standard at 29 CFR 1910.134 because the problems addressed by these requirements are national in scope. In this regard, the revision offers hundreds of thousands of employers across the nation an opportunity to adopt an additional protocol to use in assessing respirator fit among their employees. Therefore, the revision

would provide employers in every state with an alternative means of complying with the fit testing requirements specified in paragraph (f) of OSHA's Respiratory Protection Standard.

#### E. State Plans

Section 18(c)(2) of the OSH Act (29 U.S.C. 667(c)(2)) requires State-plan States to adopt mandatory standards promulgated by OSHA. However, compliance with the CNP REDON protocol provides employers with an alternative to the existing requirements for fit testing protocols specified in its Respiratory Protection Standard; therefore, the alternative is not, itself, a mandatory standard. Accordingly, State-plan States are not obligated to adopt the final provisions that result from this rulemaking. Nevertheless, OSHA strongly encourages the 24 states and two territories with their own State plans to revise their current Respiratory Protection Standard to adopt the CNP REDON fit testing protocol based on this final rulemaking.

OSHA believes that adopting this revision would provide employers in the State-plan states and territories with economic benefits that may accrue from its enactment, while protecting the safety and health of employees who use respirators against airborne hazardous substances in the workplace. These State-plan states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to state and local government employees only.

#### F. Unfunded Mandates

OSHA reviewed the revision according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. As discussed above in section IV.B (Preliminary Economic Analysis and Regulatory Flexibility Certification) of this preamble, the Agency has made a determination that the revision imposes no additional costs on any private or public sector entity. The substantive content of the revision applies only to employers whose employees use respirators for protection against airborne workplace contaminants, and compliance with the revision would be strictly optional for these employers. Accordingly, the revision would require no additional

expenditures by either public or private employers.

The Agency's standards do not apply to state and local governments, except in states that have voluntarily elected to adopt a State Plan approved by the Agency. Consequently, the revision does not meet the definition of a "Federal intergovernmental mandate" (see section 421(5) of the UMRA (2 U.S.C. 658(5))). In conclusion, the revision does not mandate that state, local, and tribal governments adopt new, unfunded regulatory obligations.

#### *G. Applicability of Existing Consensus Standards*

When OSHA promulgated its original respirator fit testing protocols on January 8, 1998, under Appendix A of its final Respiratory Protection Standard (29 CFR 1910.134), no national consensus standards addressed these protocols. However, the American National Standards Institute (ANSI) subsequently developed a national consensus standard on fit testing protocols as an adjunct to its respiratory-protection program, ANSI Z88.2-1992. ANSI approved this national consensus standard, entitled "Respirator Fit Testing Methods," on June 8, 2001 as ANSI Z88.10-2001.

Paragraph 7.3 of ANSI Z88.10-2001 provides the requirements for conducting the CNP fit test, including requirements for test instrumentation and administering the fit test; these requirements are consistent with the CNP fit testing requirements specified in 1998 by OSHA in Part I.C.4 of its Respiratory Protection Standard. In addition, section 9 and Table 1 of ANSI Z88.10-2001 describe the exercises required during CNP fit testing; these required exercises duplicate the exercises described in the CNP REDON protocol, except that the second respirator redonning is optional under the ANSI standard.<sup>7</sup> However, paragraph 9.2 of the ANSI standard specifies that one optional exercise must be included with the required exercises.

OSHA concludes that the CNP REDON protocol adopted in this rulemaking closely matches the requirements of the recent ANSI Z88.10-2001 standard. The CNP REDON protocol relies on the CNP test procedures and instrumentation described in paragraphs (a) and (c) of Part I.C.4 in Appendix A of the Respiratory Protection Standard, which

<sup>7</sup> Other optional exercises include deep breathing, side-to-side head movement, up-and-down head movement, stepping up and down, a second normal breathing exercise, grimacing followed by normal breathing, painter or sand-blaster movements, and other job-specific movements.

are similar to requirements specified in paragraph 7.3 of the ANSI standard. Any differences between these OSHA requirements and the provisions of the ANSI standard appear to be minor. Additionally, the fit testing exercises in the CNP REDON protocol are the same exercises described in the ANSI standard when a second respirator redonning is selected as the optional exercise. OSHA also is requiring employers who use the CNP REDON protocol to calculate fit factors using the harmonic-mean equation provided in the final rule; this equation is consistent with the equation described for the ambient-aerosol protocol in Appendix A of OSHA's Respiratory Protection Standard.

#### *H. List of Subjects in 29 CFR Part 1910*

Hazardous substances; Health; Occupational safety and health; Quantitative fit testing; Respirators; Respirator selection.

#### *I. Authority and Signature*

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this notice. Accordingly, the Agency issues this final rule under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Section 107, Contract Work Hours and Safety Standards Act (Construction Safety Act; 40 U.S.C. 333); Section 41, Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5-2002 (67 FR 65008); and 29 CFR part 1911.

Signed at Washington, DC on July 29, 2004.

**John L. Henshaw,**  
Assistant Secretary of Labor.

#### **IV. Amendments to the Standard**

■ For the reasons stated in the preamble, the Agency amends 29 CFR part 1910 as follows:

#### **PART 1910—[AMENDED]**

#### **Subpart I—[Amended]**

■ 1. Revise the authority citation for subpart I of part 1910 to read as follows:

**Authority:** Sections 4, 6 and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Section 107, Contract Work Hours and Safety Standards Act (the Construction Safety Act; 40 U.S.C. 333); Section 41, Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); and Secretary of Labor's Order Nos. 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), 3-2000 (65 FR

50017), or 5-2002 (67 FR 65008), as applicable.

Sections 29 CFR 1910.132, 1910.134, and 1910.138 also issued under 29 CFR part 1911.

Sections 29 CFR 1910.133, 1910.135, and 1910.136 also issued under 29 CFR part 1911 and 5 U.S.C. 553.

- 2. Amend Part I in Appendix A to § 1910.134 as follows:
  - A. In Section A, revise the introductory text of paragraph 14(a).
  - B. In Section C, paragraph 4, 8th sentence, remove the name "Dynatech Nevada" and add, in its place, "Occupational Health Dynamics of Birmingham, Alabama."
  - C. In Section C, revise paragraphs 4(a)(5) and (6).
  - D. In Section C, revise paragraph 4(c)(1).
  - E. In Section C, add paragraph 5 at the end of Part I.

The revised and added text reads as follows:

#### **§ 1910.134 Respiratory protection.**

\* \* \* \* \*

#### **Appendix A to § 1910.134: Fit Testing Procedures (Mandatory)**

\* \* \* \* \*

#### **Part I. OSHA—Accepted Fit Testing Protocols**

##### *A. Fit Testing Procedures—General Requirements*

\* \* \* \* \*

14. Test Exercises. (a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the CNP quantitative fit testing protocol and the CNP REDON quantitative fit testing protocol. For these two protocols, employers must ensure that the test subjects (*i.e.*, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.5(b) of this appendix for the CNP REDON quantitative fit-testing protocol. For the remaining fit testing methods, employers must ensure that employees perform the test exercises in the appropriate test environment in the following manner:

\* \* \* \* \*

C. \* \* \*

\* \* \* \* \*

(4) \* \* \*

(a) \* \* \*

\* \* \* \* \*

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

\* \* \* \* \*

(c) \* \* \*

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails

to hold his or her breath during the test. The test subject then may be refitted and retested.

\* \* \* \* \*

5. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of Part I.C.4 of this appendix ("Controlled negative pressure (CNP) quantitative fit

testing protocol"), as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of Part I.C.4 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration, described below in Table A-1 of this appendix.

TABLE A-1.—CNP REDON QUANTITATIVE FIT TESTING PROTOCOL

Exercises <sup>1</sup>	Exercise procedure	Measurement procedure
Facing Forward .....	Stand and breathe normally, without talking, for 30 seconds .....	Face forward, while holding breath for 10 seconds.
Bending Over .....	Bend at the waist, as if going to touch his or her toes, for 30 seconds	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking .....	For about three seconds, shake head back and forth vigorously several times while shouting.	Face forward, while holding breath for 10 seconds
REDON 1 .....	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask.	Face forward, while holding breath for 10 seconds.
REDON 2 .....	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again.	Face forward, while holding breath for 10 seconds.

<sup>1</sup> Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{[1/FF_1 + 1/FF_2 + \dots 1/FF_N]}$$

Where:

N = The number of exercises;

FF<sub>1</sub> = The fit factor for the first exercise;

FF<sub>2</sub> = The fit factor for the second exercise;

and

FF<sub>N</sub> = The fit factor for the nth exercise.

[FR Doc. 04-17765 Filed 8-3-04; 8:45 am]

BILLING CODE 4510-26-P

**SUMMARY:** The Coast Guard is establishing temporary special local regulations for the "Point Pleasant OPA/NJ Offshore Grand Prix", a marine event to be held on the waters of the Manasquan River, Manasquan Inlet and Atlantic Ocean between Point Pleasant Beach and Bay Head, New Jersey. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in the regulated area during the event.

**DATES:** This rule is effective from 9:30 a.m. to 3:30 p.m. on August 13, 2004.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket, are part of docket CCGD05-04-139 and are available for inspection or copying at Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** S. L. Phillips, Project Manager, Auxiliary and Recreational Boating Safety Section, at (757) 398-6204.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would be impracticable. The event will take place on August 13, 2004. There is not sufficient time to

allow for a notice and comment period, prior to the event. Immediate action is needed to protect the safety of life at sea from the danger posed by high-speed powerboats racing in a closed circuit.

Under 5 U.S.C. 553(d)(B)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the safety of the event participants, spectator craft and other vessels transiting the event area. However advance notifications will be made to affected waterway users via marine information broadcasts and area newspapers.

**Background and Purpose**

On August 13, 2004, the Offshore Performance Association and the New Jersey Offshore Racing Association will sponsor the "Point Pleasant OPA/NJ Offshore Grand Prix". The event will consist of approximately 35 offshore powerboats racing along an oval course on the waters of the Atlantic Ocean. A fleet of spectator vessels is expected to gather in the Atlantic Ocean near the event site to view the competition. To provide for the safety of participants, spectators and other transiting vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the races.

**Discussion of Rule**

The Coast Guard is establishing temporary special local regulations on specified waters of the Manasquan

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[CGD05-04-139]

RIN 1625-AA08

**Special Local Regulations for Marine Events; Manasquan River, Manasquan Inlet and Atlantic Ocean, Point Pleasant Beach to Bay Head, NJ**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.