for the registrant. The standard to use when determining whether disclosure would cause competitive harm for the registrant is the same standard that would apply when a registrant requests confidential treatment of confidential trade secrets or confidential commercial or financial information pursuant to Securities Act Rule 406 (17 CFR 230.406) and Exchange Act Rule 24b–2 (17 CFR 240.24b–2), each of which incorporates the criteria for non-disclosure when relying upon Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)). A registrant is not required to seek confidential treatment under the procedures in Securities Act Rule 406 and Exchange Act Rule 24b–2 if it determines that the disclosure would cause competitive harm in reliance on this instruction; however, in that case, the registrant must discuss how difficult it will be for the executive or how likely it will be for the registrant to achieve the undisclosed target levels or other factors.

* * * * *

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 11. In part 230:

■ a. The general authority citation for part 230 continues to read as set forth below; and

■ b. The specific authority citation for §§ 230.400 to 230.499 is revised; and

■ c. A specific authority citation for § 230.457 is added.

The authorities read as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l,* 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

Sections 230.400 to 230.499 issued under secs. 6, 8, 10, 19, 48 Stat. 78, 79, 81, and 85, as amended (15 U.S.C. 77f, 77h, 77j, 77s).

Sec. 230.457 also issued under secs. 6 and 7, 15 U.S.C. 77f and 77g.

* * * * *

Regulation C—Registration

■ 12. The authority citation under the undesignated center heading ''Regulation C—Registration'' is removed.

■ 13. Amend § 230.406 by:

■ a. Removing preliminary notes (1) and (2);

■ b. Adding introductory text; and

■ c. Revising paragraph (b)(2)(ii).

The addition and revision read as follows:

§ 230.406 Confidential treatment of information filed with the Commission.

Confidential treatment of supplemental information or other information not required to be filed under the Act should be requested under 17 CFR 200.83 and not under this rule. All confidential treatment requests shall be submitted in paper format only, whether or not the filer is an electronic filer. *See* Rule 101(c)(1)(i) of Regulation S–T (§ 232.101(c)(1)(i) of this chapter).

* * * * *

(b) * * *

(2) * * *

(ii) A statement of the grounds of the objection referring to and analyzing the applicable exemption(s) from disclosure under the Freedom of Information Act (5 U.S.C. 552) and a justification of the period of time for which confidential treatment is sought;

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1934

■ 14. The general authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 *et seq.;* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; and Pub. L. 111–203, 939A, 124 Stat. 1887 (2010); and secs. 503 and 602, Pub. L. 112–106, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

Subpart A—Rules and Regulations Under the Securities Exchange Act of 1934

■ 15. Amend § 240.10A–1 by revising paragraph (c) introductory text to read as follows:

§ 240.10A–1 Notice to the Commission Pursuant to Section 10A of the Act.

* * * * *

(c) A notice or report submitted to the Office of the Chief Accountant in accordance with paragraphs (a) and (b) of this section shall be deemed to be an investigative record and shall be nonpublic and exempt from disclosure pursuant to the Freedom of Information Act to the same extent and for the same periods of time that the Commission's investigative records are nonpublic and exempt from disclosure under, among other applicable provisions, 5 U.S.C. 552(b)(7). Nothing in this paragraph, however, shall relieve, limit, delay, or affect in any way, the obligation of any issuer or any independent accountant to make all public disclosures required by law, by any Commission disclosure item, rule, report, or form, or by any applicable accounting, auditing, or professional standard.

* * * * *

■ 16. Amend § 240.24b–2 by revising paragraph (b)(2) to read as follows:

§ 240.24b–2 Nondisclosure of information filed with the Commission and with any exchange.

* * * * *

(b) * * *

(2) An application making objection to the disclosure of the confidential portion. Such application shall be on a sheet or sheets separate from the confidential portion, and shall contain:

(i) An identification of the portion;

(ii) A statement of the grounds of objection referring to, and containing an analysis of, the applicable exemption(s) from disclosure under the Freedom of Information Act (5 U.S.C. 552(b)), and a justification of the period of time for which confidential treatment is sought;

(iii) A written consent to the furnishing of the confidential portion to other government agencies, offices or bodies and to the Congress; and

(iv) The name of each exchange, if any, with which the material is filed.

* * * * *

By the Commission.

Dated: September 17, 2019.

Vanessa Countryman,

Secretary.

[FR Doc. 2019–20369 Filed 9–25–19; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2015–0015]

RIN 1218–AC94

Additional Ambient Aerosol CNC Quantitative Fit Testing Protocols: Respiratory Protection Standard

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

ACTION: Final rule.

SUMMARY: OSHA is approving two additional quantitative fit testing protocols for inclusion in appendix A of the Respiratory Protection Standard. These protocols are: The modified

ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators and the modified ambient aerosol CNC quantitative fit testing protocol for filtering facepiece respirators. The protocols apply to employers in general industry, shipyard employment, and the construction industry. Both protocols are abbreviated variations of the original OSHA-approved ambient aerosol CNC quantitative fit testing protocol (often referred to as the PortaCount® protocol), but differ from the test by the exercise sets, exercise duration, and sampling sequence. These protocols will serve as alternatives to the four existing quantitative fit testing protocols already listed in appendix A of the Respiratory Protection Standard and will maintain safety and health protections for workers while providing additional flexibility and reducing compliance burdens.

DATES: The final rule becomes effective on September 26, 2019.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the agency designates Edmund Baird, Acting Associate Solicitor of Labor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, to receive petitions for review of the final rule.

FOR FURTHER INFORMATION CONTACT:

General information and press inquiries: Frank Meilinger, Director, Office of Communications; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

Technical inquiries: Natalia Stakhiv, Directorate of Standards and Guidance; telephone: (202) 693–2272; email: *stakhiv.natalia@dol.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

Appendix A of OSHA's Respiratory Protection Standard (29 CFR 1910.134) currently contains four quantitative fit testing protocols: Generated aerosol; ambient aerosol condensation nuclei counter (CNC); controlled negative pressure (CNP); and controlled negative pressure REDON. TSI Incorporated (''TSI'') proposed the ambient aerosol CNC protocol—often called the PortaCount® protocol after the CNC instrument manufactured by TSI—in 1987. OSHA allowed the ambient aerosol CNC protocol for fit testing under a compliance interpretation published in 1988. OSHA eventually incorporated that protocol into appendix A of the Respiratory Protection Standard when it revised the standard in 1998.

In 2006, TSI submitted two additional quantitative fit testing protocols to OSHA for approval and inclusion in appendix A of the Respiratory Protection Standard. These protocols were modified, abbreviated versions of the original ambient aerosol CNC protocol already approved by OSHA and listed in appendix A. OSHA published a notice of proposed rulemaking (NPRM) on January 21, 2009 (74 FR 3526) to include the two protocols in its Respiratory Protection Standard, but later concluded that they were not sufficiently accurate or reliable. OSHA withdrew the proposed rule without prejudice on January 27, 2010 (75 FR 4323), and invited the developers to resubmit the two protocols after addressing the issues of concern listed in the withdrawal notification. In 2014, TSI submitted three new quantitative fit testing protocols for OSHA approval. These three protocols also were modified, abbreviated versions of the original ambient aerosol CNC protocol, but different from the two protocols TSI submitted to OSHA in 2006.

Part II of appendix A of OSHA's Respiratory Protection Standard specifies the procedure for adding new fit testing protocols to the standard. Under that procedure, if OSHA receives an application for a new fit testing protocol meeting certain criteria, it must commence a rulemaking proceeding to consider adopting the proposed protocol. These criteria are: (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 the test data support the protocol's accuracy and reliability. TSI's 2014 application for approval of three new quantitative fit testing protocols met the second criterion. OSHA considers such proposals under the notice-and-comment rulemaking procedures specified in Section 6(b)(7) of the Occupational Safety and Health Act of 1970 (the ''Act'') (29 U.S.C. 655(b)(7)).

II. Summary and Explanation of the Final Rule

A. Proposed Rulemaking

In July 2014, TSI submitted an application requesting that OSHA approve three new quantitative fit testing protocols for inclusion in appendix A of OSHA's Respiratory Protection Standard (OSHA–2015–0015–0003). These three protocols were modified, abbreviated versions of the original ambient aerosol CNC protocol approved by OSHA and listed in appendix A, but different from the ones submitted to OSHA by TSI in 2006. TSI's application included three peer-reviewed articles (''the Richardson studies'') describing the accuracy and reliability of TSI's proposed protocols.[1] The application letter also included a copy of the 2010 ANSI/AIHA (American National Standards Institute/American Industrial Hygiene Association) Z88.10 ''Respirator Fit Testing Methods'' standard (''the ANSI standard''), which contains ''Annex A2: Criteria for Evaluating New Fit Test Methods'' (''the ANSI annex'') (OSHA–2015–0015–0007). TSI also submitted two white papers: One describing TSI's analysis of its talking exercise data and the second describing TSI's process and rationale behind the fit test exercises that were employed in the Richardson studies (OSHA–2015–0015–0001, OSHA–2015–0015–0008). OSHA determined that the information submitted in TSI's application met the criteria required for initiating a rulemaking to determine whether OSHA should approve the new protocols and add them to appendix A of the Respiratory Protection Standard. OSHA issued a notice of proposed rulemaking (NPRM) on October 7, 2016, proposing to add the new protocols and inviting public comments.

The three new protocols submitted by TSI in July 2014 included one for full-facepiece elastomeric respirators (the Fast-Full method), one for half-mask elastomeric respirators (the Fast-Half method), and one for filtering facepiece respirators (FFRs) (the Fast-FFR method). The authors of the Richardson

[1] Richardson, A.W. et al. (2014a), ''Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 31(1): 9–22 (OSHA–2015–0015–0004); Richardson, A.W. et al. (2013), ''Evaluation of a Faster Fit Testing Method for Full-Facepiece Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 30(2): 116–128 (OSHA–2015–0015–0005); Richardson, A.W. et al. (2014b), ''Evaluation of a Faster Fit Testing Method for Filtering Facepiece Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 31(1): 43–56 (OSHA–2015–0015–0006).

studies evaluated each of the three types of respirators for method performance separately, but the protocols for the Fast-Full and Fast-Half methods were identical. As such, and to prevent duplicative regulatory text, OSHA proposed to consolidate the Fast-Full and Fast-Half methods into a single protocol for approval: The modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators. OSHA further proposed to approve the Fast-FFR protocol as the modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators. No commenters objected to the consolidation and naming of the protocols during the public comment period.

The original ambient aerosol CNC protocol consists of eight test exercises, performed in the following order: Normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, grimace, bending over, and normal breathing again. The modified ambient aerosol CNC protocol for full-facepiece and half-mask elastomeric respirators differs as follows: (1) It includes only three of the eight original test exercises (bending over, head side-to-side, and head up-and-down); (2) it adds jogging-in-place as a new exercise; and (3) it reduces the total test duration from 7.2 to 2.5 minutes. The modified ambient aerosol CNC protocol for FFRs differs from the original ambient aerosol CNC protocol as follows: (1) It includes only four of the eight original test exercises (bending over, talking, head side-to-side, and head up-and-down) and (2) it reduces the total test duration from 7.2 to 2.5 minutes.

The three Richardson studies (OSHA–2015–0015–0004, OSHA–2015–0015–0005, OSHA–2015–0015–0006) compared the fit factors for the new protocols to a reference method based on the approach specified in the ANSI annex.[2] This approach requires the performance evaluation study to administer sequential paired tests using the proposed fit testing method and reference method during the same respirator donning. The reference method consisted of the standard OSHA exercises listed in Section I.A.14 of appendix A of the Respiratory Protection Standard (which are also the eight test exercises used for the original ambient aerosol CNC protocol), minus the grimace exercise, in the same order as described in the standard (*i.e.,* normal breathing, deep breathing, head side-to-side, head up-and-down, talking, bending over, normal breathing). Each exercise was performed for 60 seconds.

These protocols will serve as alternatives to the four existing quantitative fit testing protocols already listed in appendix A of the Respiratory Protection Standard and will maintain safety and health protections for workers while providing additional flexibility and reducing compliance burdens. This rule is a deregulatory action under Executive Order 13771 (82 FR 9339 (January 30, 2017)). It has annualized net cost savings estimated at $4.1 million. A detailed discussion of OSHA's estimates of the rule's benefits, costs, and cost savings is included in the Final Economic Analysis and Regulatory Flexibility Certification section.

B. Articles Supporting New Fit Testing Protocols

TSI supported its application for adding the new protocols with the three Richardson studies that indicate respectively that the proposed Fast-Half, Fast-Full, and Fast-FFR methods can identify poorly fitting respirators as well as the reference method used. Each article described a study that compared fit test results using a reference method specified in the ANSI annex with results using one of the proposed methods. The following subsections detail the methodologies and findings of the three Richardson studies.

1. Evaluation of the Fast-Half Method

a. Study Methods

The first Richardson study evaluated the Fast-Half method.[3] The study authors selected three models of NIOSH-approved, half-mask air-purifying respirators—each available in three sizes—from ''leading U.S. mask manufacturers'' equipped with P100 filters.[4] Respirators were probed with a flush sampling probe located between the nose and mouth. The study included 9 female and 16 male participants.

Each test subject donned a respirator for a five-minute comfort assessment and then performed two sets of fit test exercises, one using the reference method and another the Fast-Half method. The study authors randomized the order of the two sets of fit test exercises for each test subject. The reference method consisted of the eight standard OSHA exercises listed in Section I.A.14 of appendix A of the Respiratory Protection Standard, minus the grimace exercise, in the same order as required in the standard (*i.e.,* normal breathing, deep breathing, head side-to-side, head up-and-down, talking, bending over, normal breathing). The study subject performed each exercise for 60 seconds.

The study authors explained that they decided to exclude the grimace exercise because it ''is intended to break the respirator seal to the face'' which ''potentially results in a shift of the respirator'' (OSHA–2015–0015–0004). TSI submitted an additional explanation as to why the grimace exercise was excluded in all three Richardson studies (OSHA–2015–0015–0008). According to TSI, ''[l]ittle or no support was found for the grimace exercise among respirator fit test experts,'' and ''[t]he most common fault expressed by a number of experienced fit testers and industry experts was that the grimace cannot be consistently applied or even defined'' (*Id.*). TSI further explained that the grimace exercise is intended to break the face seal, which may not reseal in the same way for subsequent exercises. As a result, the shift in the respirator caused by grimacing can potentially confound comparisons between the fit test methods. TSI finally noted that the fit factor from the grimace exercise (if measured) is not used to calculate the overall fit factor result under the original ambient aerosol CNC method.

The Fast-Half method included four exercises: Bending, jogging-in-place, head side-to-side, and head up-and-down. Each test subject took two breaths at each extreme of the head side-to-side and head up-and-down exercises and at the bottom of the bend in the bending exercise.

Although not discussed in the Richardson study, TSI explained its rationale for selecting the exercises that were later utilized in the three Richardson studies. The exercises were identified, by TSI, as being the most rigorous for (*i.e.,* the best at) identifying poor fitting respirators in two white papers TSI prepared and submitted to OSHA (OSHA–2015–0015–0001, OSHA–2015–0015–0008). TSI reached its conclusions and selected the exercises based on a literature review, informal conversations with industry fit test experts, and in-house pilot studies.

[2] A fit factor is a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

[3] Richardson, A.W. et al. (2014a), ''Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 31(1): 9–22 (OSHA–2015–0015–0004).

[4] The authors chose not to identify the specific respirator models ''because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program'' (OSHA–2015–0015–0004).

''Talking out loud,'' ''bending,'' and ''moving head up/down'' were determined to be the three most critical exercises in determining the overall fit factor for abbreviated respirator fit test methods by Zhuang et al. (OSHA–2015–0015–0011).[5] TSI's in-house pilot fit testing studies supported the conclusions made by Zhuang et al., however, additional analysis of the TSI data by TSI uncovered an unexpected trend within the data for the talking exercise (OSHA–2015–0015–0001, OSHA–2015–0015–0008). TSI collected fit test data on subjects using consecutive sets of the seven-exercise reference method described above. TSI analyzed the frequency with which each exercise produced the lowest fit factor. Fit test data were separated into three groups: All fit tests, good-fitting fit tests, and poor-fitting fit tests. A poor-fitting fit test was defined as any test where at least one exercise failed, and a good-fitting fit test was defined as one where no exercises failed.[6] TSI's results showed that normal breathing, deep breathing, and talking rarely produced the lowest fit factor (frequency ≤3 percent) for poor-fitting full-facepiece respirators. On this basis, these three less rigorous exercises were eliminated by TSI for both the Fast-Full and Fast-Half methods. The bending exercise was the most rigorous exercise for poor-fitting full-facepiece and half-mask elastomeric respirators. Talking was the exercise among the seven exercises that most often had the lowest fit factor for good-fitting full-facepiece and half-mask respirators in the TSI pilot study. None of the other exercises stood out for half-mask respirators, but TSI reasoned that there was a lack of data suggesting that half-mask respirator fit tests should use different exercises than full-facepiece respirators (OSHA–2015–0015–0008). TSI added jogging-in-place for a fourth rigorous test exercise as part of the protocol that the Richardson authors would evaluate, reasoning that jogging ''leverages the weight of the facepiece, much like bending, but on a different axis, and also because both OSHA and ANSI currently include jogging as an alternative exercise'' (OSHA–2015–0015–0008). Jogging-in-place is an alternate (*i.e.,* elective as opposed to required) exercise in the ANSI annex. The study authors stated that jogging is ''aggressive in terms of evaluating the respirator seal'' (OSHA–2015–0015–0004).

The study authors conducted the experiments in a large chamber and added sodium chloride (NaCl) aerosol to augment particle concentrations, which they expected to range between 5,000 and 20,000 particles/cm^3 (target = 10,000 p/cm^3). The study authors used a single CPC instrument, the PortaCount® Model 8030 (TSI Incorporated, Shoreview MN), for sampling and valuation. They connected the instrument to two equal-length sampling tubes. The first tube sampled particle concentrations inside the facepiece, and the second tube sampled the ambient particle concentration. The authors used TSI software to switch between sampling lines and to record concentration data.

During the reference method, for each exercise, the ambient sampling tube was first purged for four seconds before an ambient sample was taken for 5 seconds, followed by an 11-second purge of the in-facepiece sampling tube and a 40-second in-facepiece sample. The reference method took a total of 429 seconds (7 minutes 9 seconds) to complete.

For the reference method, the authors calculated a fit factor for each exercise by dividing the mean ambient concentration for that exercise by the in-facepiece concentration taken during each exercise (average of the five-second ambient measurements before and after the exercise). The harmonic mean of the seven exercise fit factors equaled the overall fit factor. During the first exercise of the Fast-Half method (bending over), the ambient sampling tube was first purged for 4 seconds before an ambient sample was taken for five seconds; the in-facepiece sampling tube was then purged for 11 seconds and a sample was then taken from inside the mask for 30 seconds. No ambient sample was taken during the next two exercises (jogging and head side-to-side)—just one 30-second in-facepiece sample was collected for each exercise. For the last exercise (head up-and-down), a 30-second in-facepiece sample was taken, after which a 4-second ambient purge and 5-second ambient sample were conducted. The Fast-Half method took a total of 149 seconds (2 minutes 29 seconds) to complete.

For the Fast-Half method, the ambient concentration was calculated by taking the mean of two measurements—one before the first exercise and one after the last exercise. The authors calculated fit factors for each exercise by dividing the in-facepiece concentration taken during that exercise by the mean ambient concentration. As with the reference method, the harmonic mean of the four exercise fit factors represented the overall fit factor. A minimum fit factor of 100 is required in order to be regarded as an acceptable fit for half-mask respirators under appendix A of the Respiratory Protection Standard.

To ensure that respirator fit was not significantly altered between the two sets of exercises, a 5-second normal breathing fit factor assessment was included before the first exercise set, between the two sets of exercises and at the completion of the second exercise set. If the ratio of the maximum to minimum of these three fit factors was greater than 100, this experimental trial was excluded from data analysis.

b. Richardson Study Results

The ANSI annex specifies that an exclusion zone within one coefficient of variation for the reference method must be determined. The exclusion zone is the range of measured fit factors around the pass/fail fit factor of 100 that cannot be confirmed to be greater than 100 or less than 100 with adequate confidence and, therefore, should not be included in evaluating performance. The study authors determined the variability associated with the reference method using 48 pairs of fit factors from 16 participants. They defined the exclusion zone as fit factor measurements within one standard deviation of the 100 pass/fail value. Six pairs of fit factors were omitted by the study authors because the normal breathing fit factor ratio exceeded 100 and 5 pairs of fit factors were omitted because they were identified as outliers (> 3 standard deviations from the mean of the remaining data points). The exclusion zone calculated by the study authors ranged from 82 to 123 and did not include the five outliers. During review of the study methods, OSHA felt that omitting outliers to define a variability-based exclusion zone deviated from the usual scientific practice. Therefore, OSHA recalculated the exclusion zone with the outlier data included in the analysis (OSHA–2015–0015–0009). The recalculated exclusion zone was somewhat wider, ranging from 68 to 146.

The final dataset for the ANSI Fast-Half performance evaluation included 134 pairs of fit factors from 25 participants. The respirator models and sizes were used in nearly equal proportion. The study authors omitted eleven pairs of fit factors because the ratio of maximum to minimum normal breathing fit factors was greater than 100. They also omitted one pair due to a methodological error (sample line

[5] Zhuang et al. (2004) considered those exercises that had the lowest fit factors as the most critical in determining the overall fit factor.

[6] Pass/fail levels were 500 for full-facepiece respirators and 100 for half-mask elastomeric respirators and FFRs.

detached from respirator during test). As such, 122 pairs were included in the data analysis.

The study authors concluded that their statistical analysis indicates that the Fast-Half method met the required acceptance criteria for test sensitivity, predictive value of a pass, predictive value of a fail, test specificity, and kappa statistic[7] as defined in the ANSI annex (see Table 1). The same was indicated by OSHA's statistical analysis, utilizing the wider OSHA-recalculated exclusion zone, which excluded an additional three pairs for a total of nine pairs excluded and 119 pairs included in the analysis. OSHA therefore agrees with the study authors that the Fast-Half method can identify poorly fitting respirators at least as well as the reference method.

2. Evaluation of Fast-Full Method

a. Study Methods

The second Richardson study evaluated the Fast-Half method.[8] The study authors selected three models of NIOSH-approved, full-facepiece air-purifying respirators from ''leading U.S. mask manufacturers'' equipped with P100 filters. Each model was available in three sizes. Respirators were probed with a non-flush sampling probe inside the nose cup, extending 0.6 cm into the breathing zone. The study included 11 female and 16 male participants. The reference method, choice of exercises, PortaCount® instrument, test aerosol, and sampling sequence were identical to those used for the Fast-Half method. Appendix A of the Respiratory Protection Standard requires a minimum fit factor of 500 for full-facepiece respirators.

b. Richardson Study Results

The study authors determined the variability associated with the reference method using 54 pairs of fit factors from 17 participants. The exclusion zone was defined as fit factor measurements within one standard deviation of the 500 pass/fail value. Five pairs of fit factors were omitted because the normal breathing fit factor ratio exceeded 100, and three pairs of fit factors were omitted because they were identified as outliers (≤ 3 standard deviations from the mean of the remaining data points). The exclusion zone calculated by the study authors ranged from 345 to 726 and did not include the three outliers. OSHA recalculated the exclusion zone with the outlier data included in the analysis (OSHA–2015–0015–0009). The recalculated exclusion zone determined by OSHA was somewhat wider ranging from 321 to 780.

The final dataset for the ANSI Fast-Full performance evaluation included 148 pairs of fit factors from 27 participants. The respirator models and sizes were used in nearly equal proportion. Eleven pairs were omitted because the ratio of maximum to minimum normal breathing fit factors was greater than 100; one pair was omitted due to an observational anomaly (a torn piece of a cleaning wipe was observed in the respirator during the test); 136 pairs were included in the data analysis.

The study authors concluded that their statistical analysis indicates that the Fast-Full method met the required acceptance criteria for test sensitivity, predictive value of a pass, predictive value of a fail, test specificity, and kappa statistic as defined in the ANSI annex (see Table 1). The same was indicated by OSHA's statistical analysis, utilizing the wider OSHA-recalculated exclusion zone, which excluded an additional three pairs for a total of 15 pairs excluded and 133 pairs included in the analysis. OSHA therefore agrees with the study authors that the Fast-Full method can identify poorly fitting respirators at least as well as the reference method.

3. Evaluation of Fast-FFR (Filtering Facepiece Respirator) Method

a. Study Methods

The third Richardson article evaluated the Fast-FFR method.[9] Ten models of NIOSH-approved N95 FFRs from six ''leading U.S. mask manufacturers'' were selected for study.[10] The different models were selected to represent a range of styles: six cup-shaped, two horizontal flat-fold, and two vertical flat-fold models. No information was provided in the publication about whether models were available in different sizes. However, at OSHA's request, TSI submitted the following additional information regarding the choice of respirators (OSHA–2015–0015–0010):

> The study plan for FFR called for 10 N95 FFR. Unlike elastomeric respirators, FFR designs vary widely and are typically not offered in different sizes. The authors felt it was important to use a variety of designs that represent the styles currently available in the US. Of the 10 models used, 6 were cup-shaped, 2 were vertical-fold, and 2 were horizontal-fold designs. The cup-shaped style is by far the most common, which is why 6 of the 10 model selected have that fundamental design. Four flat-fold designs (2 vertical-fold and 2 horizontal-fold) models are also included.

Respirators were probed with a flush sampling probe located between the nose and mouth. Lightweight sample tubing and neck straps were used to ensure the tubing did not interfere with respirator fit. Twenty-nine participants (11 female; 18 male) were included in the study. The reference method, test aerosol, and most other study procedures were analogous to those used for the Fast-Half and Fast-Full methods. However, the Fast-FFR method employed these four exercises: Bending, talking, head side-to-side, and head up-and-down with the same sampling sequence and durations as the other test protocols. The talking exercise replaces the jogging exercise used in the Fast-Half and Fast-Full methods. TSI decided not to eliminate the talking exercise for FFRs even though their pilot study indicated that it rarely produces the lowest fit factor (OSHA–2015–0015–0008). They felt from their own experience that jogging does not represent the kind of motions that FFR wearers do when using the respirator (OSHA–2015–0015–0008). TSI also indicated that the sampling probe configured on lightweight FFR respirators caused the respirator to pull down and away from the face during jogging creating unintentional leakage. A PortaCount® Model 8038 operated in the N95 mode (TSI Inc., Shoreview MN) was used to measure aerosol concentrations throughout the experiments. The particle concentrations in the test chamber were expected to be greater than 400 p/cm^3. A minimum fit factor of 100 is required in order to be regarded as an acceptable fit for these types of respirators under appendix A of the Respiratory Protection Standard.

b. Richardson Study Results

The study administered sequential paired fit tests using the Fast-FFR

[7] The kappa statistic is a measure of agreement between the proposed and reference fit test methods. It compares the observed proportion of fit tests that are concordant with the proportion expected if the two tests were statistically independent. Kappa values can vary from −1 to +1. Values close to +1 indicate good agreement. ANSI/AIHA recommends kappa values >0.70.

[8] Richardson, A.W. et al. (2013), ''Evaluation of a Faster Fit Testing Method for Full-Facepiece Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 30(2): 116–128 (OSHA–2015–0015–0005).

[9] Richardson, A.W. et al. (2014b), ''Evaluation of a Faster Fit Testing Method for Filtering Facepiece Respirators Based on the TSI PortaCount,'' Journal of the International Society for Respiratory Protection 31(1): 43–56 (OSHA–2015–0015–0006).

[10] The authors chose not to identify the specific respirator models ''because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program'' (OSHA–2015–0015–0006).

method and a reference method according to the ANSI annex. The study authors randomized the order of the two sets of fit test exercises for each test subject. The study authors determined the variability associated with the reference method using 63 pairs of fit factors from 14 participants. They defined the exclusion zone as fit factor measurements within one standard deviation of the 100 pass/fail value. Two pairs of fit factors were omitted by the study authors because the normal breathing fit factor ratio exceeded 100, and six pairs of fit factors were omitted because they were identified as outliers (>3 standard deviations from the mean of the remaining data points). The exclusion zone calculated by the study authors ranged from 78 to 128 and did not include the six outliers. OSHA recalculated the exclusion zone with the outlier data included in the analysis (OSHA–2015–0015–0009). The recalculated exclusion zone was somewhat wider, ranging from 69 to 144.

The final dataset for the ANSI Fast-FFR performance evaluation included 114 pairs of fit factors from 29 participants. The respirator models were used in nearly equal proportion. The authors omitted two pairs because the ratio of maximum to minimum normal breathing fit factors was greater than 100, leaving 112 pairs for the data analysis.

The study authors concluded that their statistical analysis indicates that the Fast-FFR method met the required acceptance criteria for test sensitivity, predictive value of a pass, predictive value of a fail, test specificity, and kappa statistic as defined in the ANSI annex (see Table 1). The same was found by OSHA's statistical analysis, utilizing the wider OSHA-recalculated exclusion zone, which excluded an additional four pairs for a total of 11 pairs excluded and a 102 pairs included in the analysis. OSHA therefore agrees with the study that the Fast-FFR method can identify poorly fitting respirators at least as well as the reference method.

TABLE 1—COMPARISON OF FIT TEST PROTOCOLS WITH ANSI CRITERIA

	ANSI Z88.10	Fast-full	Fast-half	Fast-FFR
Sensitivity	≥0.959	0.98	0.96	1.00
PV Pass	≥0.95	0.98	0.97	1.00
Specificity	≥0.50	0.98	0.97	0.85
PV Fail	≥0.50	0.98	0.93	0.93
Kappa	≥0.70	0.97	[1] 0.89	[1] 0.89

[1] The kappa values in the table are those determined using the OSHA recalculated exclusion zone. The kappa values reported by the study authors using a narrower exclusion zone were 0.90 and 0.87, respectively, for the Fast-Half and Fast-FFR methods.
Other statistical values were the same for both OSHA and study author exclusion zone determinations.

C. Consensus Standards

While appendix A of OSHA's Respiratory Protection Standard specifies the procedure for adding new fit testing protocols to the standard, it does not specify any particular method(s) or criteria for evaluating a new fit test. Section 6(a) of the Act directs the Secretary of Labor to promulgate by rule ''as an occupational safety or health standard any national consensus standard . . . unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees.'' 29 U.S.C. 655(a). Section 6(b)(8) of the Act further states: ''Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the **Federal Register** a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.'' 29 U.S.C. 655(b)(8). And OSHA has a long history of considering national safety and health consensus standards, such as ANSI and NFPA (National Fire Protection Association), in developing its own standards.

The National Technology Transfer and Advancement Act of 1995 similarly endorses agencies' use of national consensus standards: ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' Public Law 104–113, section 12(d), 110 Stat. 775, 783 (1996), 15 U.S.C. 272 note. ANSI/AIHA is such a voluntary consensus standards body, whose standards, including Z88.10, are widely recognized and accepted by the industrial hygiene community. OSHA concurs with ANSI that ''this annex [A2] provides a specific procedure for evaluating fit test methods against the current body of knowledge.'' OSHA therefore considers the annex's procedure to be a valid, acceptable method for evaluating new fit test protocols (ANSI/AIHA, 2010).

D. Comments to the Proposal

In the October 2016 NPRM, OSHA preliminarily determined that the new protocols met the sensitivity, specificity, predictive value, and other criteria outlined in the ANSI annex and would, therefore, provide employees with at least as much protection as the reference method. That reference method consisted of the standard OSHA exercises listed in Section I.A.14 of appendix A of the Respiratory Protection Standard (which are the eight test exercises used for the original ambient aerosol CNC protocol), minus the grimace exercise, in the same order as described in the standard (*i.e.,* normal breathing, deep breathing, head side-to-side, head up-and-down, talking, bending over, normal breathing). OSHA further concluded that it was reasonable to remove the grimace exercise from the reference method during the method comparison testing, because its inclusion would unpredictably impact respirator fit (see Question #10 below for a more detailed discussion). After having considered the comments submitted in response to the NPRM (discussed below), OSHA has concluded that it is appropriate to amend appendix A of the Respiratory Protection standard to include the proposed fit test protocols.

In the NPRM, OSHA invited public comment on the accuracy and reliability of the proposed protocols, their effectiveness in detecting respirator leakage, and their usefulness in selecting respirators that will protect employees from airborne contaminants in the workplace. OSHA invited public comment on the following specific questions:

1. Were the three studies described in the peer-reviewed journal articles well controlled and conducted according to

accepted experimental design practices and principles?

2. Were the results of the three studies described in the peer-reviewed journal articles properly, fully, and fairly presented and interpreted?

3. Did the three studies treat outliers appropriately in determination of the exclusion zone?

4. Will the two proposed protocols generate reproducible fit testing results?

5. Will the two proposed protocols reliably identify respirators with unacceptable fit as effectively as the quantitative fit testing protocols, including the OSHA-approved standard PortaCount® protocol, already listed in appendix A of the Respiratory Protection Standard?

6. Did the protocols in the three studies meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI/AIHA Z88.10–2010, Annex A2, Criteria for Evaluating Fit Test Methods?

7. Are the specific respirators selected in the three studies described in the peer-reviewed journal articles representative of the respirators used in the United States?

8. Does the elimination of certain fit test exercises (*e.g.,* normal breathing, deep breathing, talking) required by the existing OSHA-approved standard PortaCount® protocol impact the acceptability of the proposed protocols?

9. Is the test exercise, jogging-in-place, that has been added to the Fast-Full and Fast-Half protocols appropriately selected and adequately explained? Should the jogging exercise also be employed for the Fast-FFR protocol? Is the reasoning for not replacing the talking exercise with the more rigorous jogging exercise in the Fast-FFR protocol (as was done in Fast-Full and Fast-Half) adequately explained?

10. Was it acceptable to omit the grimace from the reference method employed in the studies evaluating performance of the proposed fit testing protocols? Is it appropriate to exclude the grimace completely from the proposed protocols, given that it is not used in the calculation of the fit factor result specified under the existing or proposed test methods? If not, what other criteria could be used to assess its inclusion or exclusion?

11. The protocols in the three studies specify that participants take two deep breaths at the extreme of the head side-to-side and head up-and-down exercises and at the bottom of the bend in the bend-forward exercise. According to the developers of these protocols, the deep breaths are included to make the exercises more rigorous and reproducible from one subject to the next. Are these additional breathing instructions adequately explained in the studies and in the proposed amendment to the standard? Are they reasonable and appropriate?

12. Does OSHA's proposed regulatory text for the two new protocols offer clear instructions for implementing the protocols accurately?

OSHA received 27 comments from 25 separate individuals, with one individual submitting three separate comments (OSHA–2015–0015–0015 to OSHA–2015–0015–0042). In addition, TSI submitted a comment several months after the close of the comment period (OSHA–2015–0015–0047). OSHA added TSI's comment to the docket as a late submission in the interest of full disclosure but did not take it into account.

Of the 27 timely comments, six did not specifically address any of OSHA's specific questions, but were generally in favor of the proposed protocols (OSHA–2015–0015–0016, OSHA–2015–0015–0018, OSHA–2015–0015–0019, OSHA–2015–0015–0020, OSHA–2015–0015–0030, OSHA–2015–0015–0039). Among other things, these comments agreed that the abbreviated protocols would save time and resources and would increase employer compliance with safety and health regulations.

OSHA addresses below the comments that addressed the NPRM's specific questions:

1. Were the three studies described in the peer-reviewed journal articles well controlled and conducted according to accepted experimental design practices and principles?

The majority of concerned comments about the proposed protocols related to the experimental design and methods used in the three Richardson studies supporting the proposed protocols. The most common of these criticisms was that the testing was not representative of ''real world'' settings (OSHA–2015–0015–0022, OSHA–2015–0015–0025, OSHA–2015–0015–0026, OSHA–2015–0015–0027, OSHA–2015–0015–0032, OSHA–2015–0015–0033, OSHA–2015–0015–0040, OSHA–2015–0015–0041, OSHA–2015–0015–0042). For example, one commenter asserted that the environment of the test chambers used in the three Richardson studies was ''too controlled'' and that the studies ''did not allow for variables encountered by fit test providers when conducting fit testing in real world settings'' (OSHA–2015–0015–0026). Another commenter stated: ''In an uncontrolled environment many factors, including but not limited to, ventilation, doors being opened, and room temperature can greatly affect the particle count in a relatively short time'' (OSHA–2015–0015–0040).

Regarding these comments, OSHA would like to stress that the proposed protocols were evaluated using the criteria outlined in Annex A2 of the ANSI/AIHA Z88.10–2010 standard, which does not require uncontrolled testing conditions with variables such as fluctuating climate, temperature, elevation, air currents, ventilation, etc. OSHA considers the ANSI annex method to be a valid method for evaluating new fit test protocols.

Many of these comments related specifically to the use of generated aerosols in the three Richardson studies (OSHA–2015–0015–0022, OSHA–2015–0015–0026, OSHA–2015–0015–0033, OSHA–2015–0015–0041). For example, one commenter stated:

> The PortaCount® was designed and marketed to be used for conducting quantitative fit tests using room aerosols, whereas the supporting studies were conducted in a test chamber using a generated aerosol. Concentrations of room aerosols are typically about $1x10^3$ p/cc, whereas in these studies the average challenge concentrations were about $2x10^4$ p/cc. . . . I would recommend that the protocols not be accepted until these validation tests are conducted using ambient aerosols. . . . (OSHA–2015–0015–0033).

Another commenter questioned why the study authors used generated aerosol in a test chamber when their goal was to prove the acceptability of a new ambient aerosol test protocol (OSHA–2015–0015–0041).

None of the three Richardson studies, however, employed a ''generated aerosol'' atmosphere as described in the ANSI/AIHA Z88.10 standard; instead, they used ''the ambient laboratory aerosol which was augmented by NaCl particles from a TSI Model 8026 Particle Generator'' (OSHA–2015–0015–0004, OSHA–2015–0015–0005, OSHA–2015–0015–0006). This approach is allowed by ANSI/AIHA in Annex A2, which states that ''a proposed modification to an accepted QNFT [quantitative fit testing] protocol can be evaluated using the accepted protocol for that instrument as the reference standard.'' As some commenters noted (OSHA–2015–0015–0031, OSHA–2015–0015–0041), it is often necessary to augment the ambient environment when using the original OSHA-approved ambient aerosol CNC fit test method in a relatively clean office environment. The TSI particle generator is one of several approaches commonly used (OSHA–2015–0015–0051, OSHA–2015–0015–0050). In fact, as noted by one commenter, technicians sometimes burn candles or incense in order to reach and

maintain ambient particle counts (OSHA–2015–0015–0032). OSHA has concluded that there is no material difference between the experimental atmosphere employed in the three Richardson studies and the atmosphere commonly used for quantitative fit testing with the ambient aerosol CNC method.

Other commenters expressed concerns that the ambient and purge times were too short (OSHA–2015–0015–0022, OSHA–2015–0015–0026, OSHA–2015–0015–0027, OSHA–2015–0015–0032, OSHA–2015–0015–0033, OSHA–2015–0015–0036, OSHA–2015–0015–0038, OSHA–2015–0015–0041, OSHA–2015–0015–0042). For example, one commenter recommended that the proposed protocols ''should provide for suitable ambient and respirator purge durations to address the full range of particle concentrations that the device is recommended for use in instead of selecting a duration based on the optimum conditions that were selected for the studies. . . .'' (OSHA–2015–0015–0026). Several commenters were also concerned that each ambient sample conducted at the beginning and end of the new protocols lasted only five seconds (OSHA–2015–0015–0032, OSHA–2015–0015–0036, OSHA–2015–0015–0042).

Regarding these comments, OSHA notes that for every exercise (except the grimace), the original OSHA-approved ambient aerosol CNC protocol involves a 4-second ambient purge, a 5-second ambient sample, and an 11-second mask purge, followed by a 40-second mask sample. A final 4-second ambient purge and 5-second ambient sample occur after the last 40-second exercise (normal breathing) mask sample. The proposed protocols employ the same 4-second ambient purge, 5-second ambient sample, and 11-second mask purge, followed by 4 consecutive 30-second mask samples during each of the 4 exercises, and a final 4-second ambient purge and 5-second ambient sample. The ambient purge and sample times are the same. The new protocols differ from the original OSHA-approved sampling protocol in these ways: The ambient environment is measured only at the beginning and end of the exercises and not between each exercise, mask purging occurs just once (after the first ambient sample), and mask sampling time is 30 seconds rather than 40 seconds. Additionally, requirements for conducting the fit test in an environment with an adequate particle concentration also did not change; they have been standard practice for the ambient aerosol CNC fit test method since its inception and approval by OSHA.

Regarding ambient measurements, the only difference between the new protocols and the original OSHA-approved protocol is that the new protocols take measurements at the beginning and end of the exercises, while the original protocol does so between each exercise. Because the total duration of the new protocols is much shorter than the original—2.5 minutes versus 7.2 minutes—OSHA has concluded that there is no need to take periodic samples between exercises. In particular, the time between the two ambient samples in the proposed protocol is 2 minutes 15 seconds, compared to 55 seconds between each ambient sample in the original protocol. This minor difference is unlikely to introduce any significant errors if fit testers follow standard practice: (1) Ensure the aerosol concentration falls between 1,000 and 30,000 particles/cm^3 (p/cm^3) for filters with a NIOSH designation of N/R/P–99 or 100, and 30 to 1,500 p/cm^3 for filters with a N/R/P–95 designation; and (2) do not augment the ambient environment if the concentration exceeds 8000 p/cm^3 or 800 p/cm^3 for the 99/100 or the 95 filters, respectively (OSHA–2015–0015–0049).

Two commenters expressed concern over eliminating purging between exercises altogether (OSHA–2015–0015–0022, OSHA–2015–0015–0038). But there is no reason for purging between the different exercises in the proposed protocol because the instrument continues to sample from the same environment (inside the facepiece) throughout the exercises. Particles measured during the first few seconds of transition from one exercise to the next will have almost no influence on the average concentration over a 30-second exercise sampling period.

Purging ensures that the sensing volume evaluates particles from the correct environment and is only necessary when switching between ambient and mask samples or vice versa. The proposed protocols do not switch between ambient and mask sampling during the exercises, so purging is not required.

Some commenters requested further review of the methodology of the three Richardson studies or further validation testing by a ''third party'' (OSHA–2015–0015–0029, OSHA–2015–0015–0040). OSHA notes that the studies were conducted by a third party, Battelle Memorial Institute, and the study methods were approved by Battelle's Institutional Review Board. In addition, NIOSH stated that their ''review determined that the three methods met the criteria contained in the ANSI/AIHA Z88.10–2010, Annex A2'' (OSHA–2015–0015–0031). And one commenter who had some concerns about the proposed protocols conceded that the ''referenced peer-reviewed articles in J. of Respiratory Protection appear to meet the mathematical and statistical criteria we expect'' (OSHA–2015–0015–0024). Finally, the publication of the three Richardson studies in a peer-reviewed industrial hygiene journal suggests they were well-controlled and conducted according to accepted experimental design practices and principles. In summary, OSHA determined that the public comments did not identify any significant shortcomings in the experimental design and methodology used in the three studies.

2. Were the results of the three studies described in the peer-reviewed journal articles properly, fully, and fairly presented and interpreted?

Although critical of the fact that the studies were conducted in a test chamber as opposed to a real world setting, one commenter stated ''that under the specific set of conditions that the tests were performed that they were presented well'' (OSHA–2015–0015–0026). But another commenter expressed that it was ''impossible to determine if the articles were properly, fully, and fairly presented and interpreted'' because the articles did not provide data tables listing ''respirator make, model, style, size, individuals tested, and the paired results of the new test and the reference test'' as outlined in the ANSI annex (OSHA–2015–0015–0038). The annex recommends—but does not require—such tables, and it is often difficult to publish a peer-reviewed article containing a complete dataset. Regardless, OSHA reviewed the full datasets provided by TSI as part of the review of the study protocols, and no commenters asked to see the datasets. In summary, OSHA finds that the public comments did not identify any significant shortcomings in the way that the results of the three journal articles were presented or interpreted.

3. Did the three studies treat outliers appropriately in determination of the exclusion zone?

While OSHA disagreed with the studies' omissions of outliers in calculating exclusion zones, OSHA recalculated exclusion zones with the outlier data included, and the results of the re-analysis did not change any of the studies' conclusions. In addition, NIOSH considered the study authors' identification of outliers to be ''a reasonable method for diagnosing/identifying outliers'' (OSHA–2015–

0015–0031). Finally, no commenters expressed concern about the treatment of outliers. OSHA concludes that the treatment of outliers in the studies did not undermine any of the studies' results or conclusions.

4. Will the two proposed protocols generate reproducible fit testing results?

Some commenters questioned the reproducibility of fit testing results using the two proposed protocols (OSHA–2015–0015–0022, OSHA–2015–0015–0042), but did not offer any compelling data or research suggesting their non-reproducibility. One of these commenters had concerns based on NIOSH's recommendation that OSHA (OSHA–2015–0015–0042) conduct additional research to gather evidence for a more informed decision. The commenter stated:

> With this recommendation OSHA should not accept a protocol that still needs further evidence to show it will produce reproducible fit testing results. There are too many respirators and employees in hazardous conditions to allow a protocol to move forward that isn't fully vetted and accurate (OSHA–2015–0015–0042).

OSHA believes this commenter took NIOSH's comment out of context. The NIOSH response to this question—in its entirety—is the following:

> The studies used the OSHA-accepted ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol as the reference method. This method has been shown to produce reproducible fit testing results [Zhuang et al. 1998; Coffey et al. 2002]. Using the procedures and requirements of ANSI Z88.10–2010, the abbreviated methods provided results comparable to the reference method. Therefore, the proposed protocols are anticipated to generate reproducible results. NIOSH recommends that additional research be conducted to provide evidence for a more informed decision (OSHA–2015–0015–0031).

While additional research is always valuable, OSHA agrees with NIOSH that the proposed protocols are anticipated to generate reproducible results. The proposed protocols were evaluated based on the approach specified in the ANSI annex, which provides a specific procedure for evaluating fit test methods ''against the current body of knowledge'' and is considered a valid method by much of the industrial hygiene community. Having met the criteria of the ANSI annex, OSHA concludes that the proposed protocols will generate reproducible fit testing results.

5. Will the two proposed protocols reliably identify respirators with unacceptable fit as effectively as the quantitative fit testing protocols, including the OSHA-approved standard PortaCount® protocol, already listed in appendix A of the Respiratory Protection Standard?

Several commenters questioned not only the acceptability of the proposed protocols, but also the validity of the original ambient aerosol particle counting quantitative method already accepted by OSHA and listed in appendix A (OSHA–2015–0015–0022, OSHA–2015–0015–0026, OSHA–2015–0015–0027, OSHA–2015–0015–0029). Some of these commenters were also of the opinion that the CNP-based fit testing methods are superior to other quantitative fit testing methods. One commenter (OSHA–2015–0015–0042) stated that the following NIOSH ''statement raises major concerns to the ability & proven accuracy of this proposed protocol to identify respirators with unacceptable fit'':

> Evidence is not available in the literature to assess whether the two proposed protocols reliably identify respirators with unacceptable fit as effectively as the other accepted quantitative fit testing protocols (generated aerosol and controlled negative pressure (CNP)). It is recommended that further side-by-side studies be conducted to test the equivalency of the new PortaCount Fast-Fit methods in identifying poorly fitting respirators as effectively as the OSHA-accepted CNP testing; potentially, tests using other ''generated aerosols'' would be needed to determine whether the methods are equivalent (OSHA–2015–0015–0031).

Although NIOSH recommended future research, it nonetheless recommended that OSHA accept the proposed protocols. In its review of the three Richardson studies, NIOSH also determined that the proposed protocols conform to the requirements of the ANSI annex.

The validity of the original OSHA-approved ambient aerosol CNC fit testing protocol was never under question in this rulemaking. Appendix A of OSHA's Respiratory Protection Standard states that quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit has ''been demonstrated to be acceptable.'' In addition, the members of the ANSI/AIHA Z88.10 ''Respirator Fit Testing Methods'' committee, who represent many of the nation's leading respiratory protection experts, opted to retain, rather than reject, this method as an acceptable quantitative fit testing method when they updated the national consensus standard in 2010. Furthermore, the proposed protocols were evaluated using the method described in the ANSI annex, which does not require a statistical comparison against the CNP method (OSHA–2015–0015–0007). Likewise, OSHA's Respiratory Protection Standard does not require that a new fit testing protocol be compared to the CNP method, or any other specific fit testing method. Moreover, just as OSHA does not rank specific makes and models of respirators, OSHA also does not rank fit testing methods. Each fit testing method has its own advantages and disadvantages.

In summary, OSHA determined that the new protocols met the sensitivity, specificity, predictive value, and other criteria outlined in the ANSI annex and will, therefore, provide employees with protections comparable to protections afforded to them by the reference method, which consisted of the standard OSHA exercises listed in Section I.A.14 of appendix A of the Respiratory Protection Standard, minus the grimace exercise, in the same order as described in the standard (*i.e.,* normal breathing, deep breathing, head side-to-side, head up-and-down, talking, bending over, normal breathing). These are the same test exercises, minus the grimace, that are utilized for both the CNC and CNP protocols. OSHA concluded that it was reasonable to remove the grimace exercise from the reference method during the method comparison testing, because its inclusion would unpredictably impact respirator fit within each pair of data comparing the current and new fit test protocols (see Question #10 below for a more detailed discussion).

6. Did the protocols in the three studies meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI/AIHA Z88.10–2010, Annex A2, Criteria for Evaluating Fit Test Methods?

One commenter stated that evaluating the sensitivity of the new protocols ''presents a quandary because the sensitivity of the standard PortaCount protocol has itself not been established'' (OSHA–2015–0015–0022). As discussed under question #5, the validity of the original OSHA-approved ambient aerosol CNC fit testing protocol is not at issue in this rulemaking.

OSHA's evaluation of the proposed protocols determined that they met the criteria outlined in the ANSI annex (see sections A–B above). In addition, NIOSH stated that their ''review determined that the three methods met the criteria contained in the ANSI/AIHA Z88.10–2010, Annex A2'' (OSHA–2015–0015–0031). Another commenter agreed that ''the submitted request has followed the defined procedures and the results fit within the statistical limits set forth in ANSI Z88.10–2010'' (OSHA–2015–0015–0035). Furthermore, OSHA

determined that the public comments did not provide any substantive data or information suggesting that the proposed protocols in the three studies did not meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI annex.

7. Are the specific respirators selected in the three studies described in the peer-reviewed journal articles representative of the respirators used in the United States?

One commenter questioned the ''very small sample of the wide range of tight sealing respirators that were used in the [studies]'' (OSHA–2015–0015–0029), and another expressed that ''the small sample size of respirators chosen for testing lends itself to being less than ideal'' (OSHA–2015–0015–0040). However, neither commenter provided specific recommendations or statistical data regarding the numbers and types of respirators that should have been selected or why. Further, the industrial hygiene research community does not require a specified sample size of respirators to assess fit testing protocols. Finally, had the respirator sample size been too small to produce reliable results, the studies likely would not have been accepted for publication in a peer-reviewed journal.

One commenter questioned why the Richardson studies included only filtering facepiece respirators without exhalation valves, noting that many users opt to wear filtering facepiece respirators with exhalation valves for comfort reasons (OSHA–2015–0015–0026). But an exhalation valve does not affect respirator fit. While the study authors did not explain how they selected the respirator models and designs, OSHA has determined that the public comments did not identify any significant shortcomings in respirator selection and believes that the models and designs selected for the three experiments were appropriately representative.

8. Does the elimination of certain fit test exercises (e.g., normal breathing, deep breathing, talking) required by the existing OSHA-approved standard PortaCount® protocol impact the acceptability of the proposed protocols?

Several commenters expressed concern over removing certain fit test exercises (OSHA–2015–0015–0021, OSHA–2015–0015–0024, OSHA–2015–0015–0025, OSHA–2015–0015–0029, OSHA–2015–0015–0032, OSHA–2015–0015–0033, OSHA–2015–0015–0038, OSHA–2015–0015–0041), but did not provide any peer-reviewed data or published research to support their opinions. Three commenters (OSHA–2015–0015–0021, OSHA–2015–0015–0025, OSHA–2015–0015–0032) expressed concern about removing the talking exercise, because they had experienced fit test failures during the talking exercise when fit testing workers. Another commenter felt that ''it doesn't make sense to eliminate [the talking] exercise simply because it wasn't the worst contributing exercise with poor fitting respirators'' (OSHA–2015–0015–0033). A third suggested retaining the head side-to-side, head up-and-down, and talking exercises because he believes they are currently the most rigorous exercises (OSHA–2015–0015–0024).

Another commenter suggested that ''the conclusion to eliminate Normal Breathing 2 (NB2) from the Fast Full Protocol is extremely subjective'' and questioned how ''NB2 [normal breathing #2] could be eliminated and UD [moving head up and down] kept if there is no correlation with the study data?'' (OSHA–2015–0015–0038). This commenter suggested increasing the purge time to improve the ability of the NB2 exercise to detect poor fits. Regarding this question, OSHA has concluded that TSI properly excluded the second normal breathing exercise. In TSI's study of the Fast-Full method, the second normal breathing exercise had the lowest fit factor 19% of the time for poor-fitting respirators. While this score normally indicates an exercise was effective at detecting poor-fitting respirators, TSI concluded that score was anomalous because the corresponding score for the first normal breathing (NB1) exercise was 0%. TSI reasoned the 19% score was a result of particles introduced into the facepiece during the preceding (bending over) exercise that were not purged (OSHA–2015–0015–0008). Increasing the purge time to clear such particles would not, as the commenter suggests, improve the ability of the NB2 exercise to detect poor fits. Instead, NB2 would likely be as ineffective as NB1, which was never the lowest fit factor for any poor-fitting respirators. This is also supported by the fact that the NB1 and NB2 exercises produced the lowest fit factors only 2% and 5% of the time, respectively, for good-fitting respirators.

One commenter noted that ''[e]limination of the normal breathing, deep breathing, and talking fit test exercises from the proposed Fast protocols has significant potential for adverse impact on PortaCount fit test results in the real world'' (OSHA–2015–0015–0022). With respect to normal breathing and talking, the commenter noted that several studies not mentioned by the three Richardson studies indicate that the first normal breathing exercise fit factor is typically lower than fit factors from all subsequent exercises and that the talking exercise also often results in a lower fit factor. But this commenter did not provide any basis to believe eliminating these exercises will put workers at risk. Indeed, he conceded that ''respirator donning has a greater effect on respirator fit than do fit test exercises'' and ''the lower fit factors produced by the talking exercise appear to be more consistent with sampling artifact than with actual exercise dynamics.'' And, as TSI explained, fit factors for the second normal breathing exercise are likely to be contaminated by prior exercises (OSHA–2015–0015–0008). Finally, this commenter offered no data or published information that suggest deep breathing is more rigorous than other exercises or that eliminating deep breathing will put workers at risk.

One commenter (OSHA–2015–0015–0029) stated that ''our experience strongly suggests that the Deep Breathing and Talking Exercises are frequently the exercises that see the lowest fit factors calculated and often are 'THE Exercises' which determine whether a respirator wear will achieve a Pass or Failure following the completion of the fit test series of exercises.'' He further suggested ''a more thorough evaluation of this change by a third party such as NIOSH–NPPTL. . . .'' Another commenter requested that a review of the studies be performed by an independent third party (OSHA–2015–0015–0040). NIOSH/NPPTL did in fact review and evaluate the studies. In the comments NIOSH submitted to OSHA, NIOSH did not express any concern over the removal of the talking exercise and ultimately ''recommend[ed] that OSHA accept the three protocols'' (OSHA–2015–0015–0031).

Regarding all these comments, the industrial hygiene community has not come to a consensus as to which test exercises must be used in a new fit testing protocol. Neither the ANSI annex nor OSHA's appendix requires any specific test exercise(s) be used in a new fit testing protocol. Further, in 2004, OSHA approved an abbreviated version of the CNP protocol, called the CNP REDON protocol, which excludes the deep breathing and talking exercises, and includes only the facing forward (same as normal breathing), bending over, and head shaking exercises. In sum, the information submitted in the public comments did not convince OSHA that the elimination of the deep breathing and talking exercises adversely impacted the acceptability of the proposed protocols,

which met the sensitivity, specificity, predictive value, and other criteria contained in the ANSI annex.

9. Is the test exercise, jogging-in-place, that has been added to the Fast-Full and Fast-Half protocols appropriately selected and adequately explained? Should the jogging exercise also be employed for the Fast-FFR protocol? Is the reasoning for not replacing the talking exercise with the more rigorous jogging exercise in the Fast-FFR protocol (as was done in Fast-Full and Fast-Half) adequately explained?

One commenter was of the opinion that ''[t]he jogging exercise, while rigorous, is not representative of real-life civilian activities'' (OSHA–2015–0015–0024). NIOSH stated that it would have liked to have seen references to support that the jogging-in-place exercise used in the protocols for elastomeric respirators was aggressive in evaluating the respirator seal. However, this did not prevent NIOSH from recommending that OSHA approve the proposed protocols (OSHA–2015–0015–0031). Furthermore, as stated above under question #8, the industrial hygiene community has not come to a consensus as to which test exercise(s) must be included in new fit testing protocols. More importantly, neither the ANSI annex nor OSHA's appendix requires that any specific test exercise(s) be used in a new fit testing protocol.

10. Was it acceptable to omit the grimace from the reference method employed in the studies evaluating performance of the proposed fit testing protocols? Is it appropriate to exclude the grimace completely from the proposed protocols, given that it is not used in the calculation of the fit factor result specified under the existing or proposed test methods? If not, what other criteria could be used to assess its inclusion or exclusion?

One commenter (OSHA–2015–0015–0026) stated that he ''seriously question[s] the choice of the study and protocol authors in removing the Grimace exercise.'' While he ''concur[s] with their statement that it cannot be consistently applied and with their statement that the fit factor if measured should not be used in calculation of the fit factor,'' his ''interpretation is that the importance of the grimace is not in the fit factor achieved during this step of the protocol but instead in the ability of the mask to re-seal after this exercise which goes to the respirator['s] proper fit.''

While NIOSH (OSHA–2015–0015–0031) ''recommends that the grimace test be included in the abbreviated protocols when used in the workplace since it is part of the currently accepted protocols,'' NIOSH agrees that the new ''protocols provide a valid reason for not including [the grimace] in the method comparison testing since it would add a non-controlled variable.'' Similarly, another commenter stated:

> The Grimace exercise is intended to break the face seal and then measure the recovery of the seal in the following exercises. By breaking the seal in the Grimace exercise during the reference protocol you have now altered the original fit of the mask and compromised the second fit test data. Therefore it makes logical sense that this exercise was eliminated from the test procedure for both the reference test and the proposed test. The fit of the mask as originally donned is consistent for both the reference test and the proposed protocol test (OSHA–2015–0015–0035).

OSHA agrees that it is reasonable to remove the grimace exercise from the reference method during the method comparison testing, because its inclusion would unpredictably impact respirator fit. Some respirator fit test protocols include the grimace exercise because it is believed that it will unseat the respirator facepiece; whether this occurs is assessed, however, only during the subsequent exercise—fit measured during the grimace exercise is not included in the calculation of overall fit. Because method comparison requires a range of fit factors (from poor- to well-fitting respirators), OSHA believes that excluding the short grimace exercise allows for a more consistent assessment of fit between the reference and new fit test protocols.

Finally, neither the ANSI annex nor the OSHA appendix specifies which exercises must be used in a new fit testing protocol. The 2010 ANSI Z88.10 standard specifically considers the grimace exercise to be elective for the particle-counting instrument quantitative fit test procedure that it describes (see Table I). And although OSHA requires the grimace exercise as part of the original ambient aerosol CNC protocol, OSHA approved an abbreviated CNP REDON protocol in 2004 that excluded the grimace exercise among four other exercises. As such, OSHA concludes that it is not necessary to add the grimace exercise to the proposed protocols.

11. The protocols in the three studies specify that participants take two deep breaths at the extreme of the head side-to-side and head up-and-down exercises and at the bottom of the bend in the bend-forward exercise. According to the developers of these protocols, the deep breaths are included to make the exercises more rigorous and reproducible from one subject to the next. Are these additional breathing instructions adequately explained in the studies and in the proposed amendment to the standard? Are they reasonable and appropriate?

OSHA received no comments regarding these questions, which suggests that the breathing instructions were adequately explained in both the studies and in the proposed amendment to the standard, and that stakeholders were not concerned about this issue.

12. Does OSHA's proposed regulatory text for the two new protocols offer clear instructions for implementing the protocols accurately?

Neither TSI nor any commenters expressed concern about the clarity of OSHA's proposed regulatory text instructions for implementing the protocols. In the absence of such comments, the only changes that OSHA has made to the proposed regulatory text include an expansion of the titles of Tables A–1 and A–2 to match the names of the new protocols exactly. OSHA did this solely for clarity, so employers correctly correlate these two new tables with the two new proposed protocols.

Several commenters expressed miscellaneous concerns that did not fall directly under any of OSHA's specific questions for public comment. OSHA addresses each in turn. One commenter was not in favor of any quantitative fit testing methods because, in his view, qualitative fit tests are more convincing to the respirator wearers themselves (OSHA–2015–0015–0017):

> [p]assing quantitative measurements may be literally orders of magnitude apart. If the machine says a 13 is passing, and a 400 is passing as well, how are the wearers of the respirators supposed to feel when they compare their numbers? (I have literally seen those numbers before entering a CBRN Defense Training Facility (CDTF) with live nerve and mustard agent; each individual was concerned that his/her mask was not as ''good'' as the other's, as they had no idea what the numbers meant.

As an initial matter, this rulemaking was not intended to compare qualitative fit tests to quantitative fit tests—employers are free to choose such tests as appropriate under appendix A of the Respiratory Protection Standard. The two new protocols will serve only as additional quantitative fit testing options to employers. That said, qualitative fit testing is not appropriate for certain respirators. In fact, the individuals described by the commenter could not have used qualitative fit testing because proper protection against CBRN (chemical, biological, radiological and nuclear) exposures

requires a full-facepiece, which must be fit tested using a quantitative method.[11]

Another commenter was concerned about shortening the protocols to less than an eight-minute period, because she thought that symptoms of claustrophobia/panic attacks might not manifest before eight minutes (OSHA–2015–0015–0021). However, the risk of claustrophobia/panic attacks is already addressed when the wearer is required, under § 1910.134(e)(1) of the Respiratory Protection Standard, to undergo a mandatory medical evaluation ''to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace.'' And the mandatory medical questionnaire in Appendix C of the standard includes a question regarding claustrophobia. In addition, OSHA is unaware of this having been an issue for respirator wearers fit tested using the CNP REDON protocol, which also lasts less than eight minutes and was approved by OSHA in 2004.

Two commenters who favored shorter protocols expressed interest in making the new protocols available on all ambient aerosol CNC-based fit testing instruments, particularly the older PortaCount® (model 8020) machines (OSHA–2015–0015–0028, OSHA–2015–0015–0030). OSHA notes that the new protocols are not restricted to any particular testing instrument because OSHA only approves fit testing protocols, not specific fit testing machines.[12] OSHA has no authority to require specific fit testing machines or models for new protocols. Employers must contact the manufacturers of CNC fit testing machines to determine which models support the new protocols.

E. Conclusions

After reviewing the comments submitted to the record, OSHA finds that the two proposed modified ambient aerosol CNC quantitative fit testing protocols are supported by peer-reviewed studies that were 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 peer-reviewed studies and comments submitted to the record, OSHA finds that the two proposed protocols meet the sensitivity, specificity, predictive value, and other criteria contained in the ANSI annex. Moreover, the proposed protocols met the criteria of the ANSI annex, and in the absence of any compelling data or research in the record that would suggest that the proposed protocols would not generate reproducible fit testing results, OSHA concludes that the proposed protocols will generate reproducible fit testing results. In summary, OSHA concludes that the two proposed protocols are sufficiently accurate and reliable to approve and include in appendix A of its Respiratory Protection Standard.

F. N95-Companion™ Technology

The original TSI PortaCount® machine (model 8020) could only be used to fit test respirators equipped with ≥99% efficient filter media (*i.e.,* N–, R–, or P–99 and 100 NIOSH filter designations). In 1998, TSI introduced the N95-Companion™ Technology, which, when combined with the PortaCount® 8020 model, could be used to fit test respirators equipped with <99% efficient filter media (*e.g.,* N95 NIOSH filter designation). TSI no longer manufactures the 8020 model, which was replaced by a second generation of PortaCount® instruments (models 8030 and 8038). TSI introduced a third generation of PortaCount® instruments (models 8040 and 8048) in November 2017. Models 8030 and 8040 can only test the most efficient filters (*i.e.,* 99 and 100 NIOSH filter designations), while models 8038 and 8048, which include the N95 Companion™ Technology already built into the machine, can test any type of filter by selecting the appropriate operating mode. Because employers are sometimes confused by this distinction, OSHA considered using this rulemaking to propose additional language to Part I.C.3 of appendix A of the Respiratory Protection Standard to reflect this technological development. The additional language proposed by OSHA did not alter the fit testing protocol or impose any new requirements on employers; it was merely intended for clarification purposes.

One commenter expressed concern over the use of the brand name ''Portacount®'' within the regulatory text, stating that ''[t]his seems to exclude other potential CNC providers'' (OSHA–2015–0015–0024). Regarding this comment, the original OSHA-approved ambient aerosol CNC protocol is often commonly referred to as the PortaCount® protocol because of the name of the CNC machines manufactured by the company (*i.e.,* TSI) that proposed the original protocol. OSHA is aware of only one other manufacturer that produces CNC instrumentation that is sold in the U.S. at this time. This new CNC instrumentation was only recently introduced into the market, so OSHA estimates that the overwhelming majority of the CNC instruments used in the U.S. at this time are still TSI PortaCount® machines. As such, OSHA determined that it is in the best interests of worker health and safety to retain the PortaCount® name within the regulatory text, as it has appeared in appendix A since 1998. This language is not intended to be exclude other manufacturers. It is intended merely to reflect that TSI's machines are those typically used for this test at this point in time. OSHA does not approve any safety equipment or require employers to use specific brands of safety equipment. However, it does sometimes refer to company or brand names when it is in the interest of safety and health. For example, appendix A of the Respiratory Protection Standard also includes the brand name (*i.e.,* Bitrex®) for the substance (*i.e.,* denatonium benzoate solution aerosol) overwhelmingly used for one of the OSHA-approved qualitative fit testing protocols. In addition, appendix A refers to the name of the company (*i.e.,* Occupational Health Dynamics) that proposed the original CNP protocol and manufacturers CNP instrumentation.

OSHA has, however, decided not to add the clarifying information about the different types of PortaCount® machines, due to commenter concerns that the inclusion of such information could create the appearance of a product endorsement. Since OSHA approves fit testing protocols rather than machines, OSHA feels that employers can contact fit testing instrument manufacturers for product specificity and capabilities.

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, which protects them 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.

OSHA has determined that the additional modified ambient aerosol CNC protocols provide employees with protection that is comparable to the protection afforded them by the existing fit testing provisions. The additional

[11] Qualitative fit tests are limited to negative pressure air-purifying respirators that must achieve a fit factor of 100 or less, *i.e.,* they may only be used to fit test half-mask, not full-facepiece, respirators. 29 CFR 1910.134(f)(6).

[12] TSI informed OSHA that the new protocols would not be available on the now-discontinued 8020 models (OSHA–2015–0010).

modified ambient aerosol CNC protocols do not replace existing fit testing protocols, but instead are alternatives 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 burden. The additional modified ambient aerosol CNC protocols reduce the total fit test duration, and therefore may reduce the compliance burden for employers that elect to use one of these protocols.

B. Final Economic Analysis and Regulatory Flexibility Certification

The rule is not economically significant under Executive Order 12866 (58 FR 51735) or a ''major rule'' under Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 804). The rule imposes no additional costs on any private- or public-sector entity and is not a significant or major rule under Executive Order 12866 or other relevant statutes or executive orders. This rulemaking increases employers' flexibility in choosing fit testing methods for employees, and the final rule does not require an employer to update or replace its current fit testing method(s) if the fit testing method(s) currently in use meets existing standards. Furthermore, because the rule offers additional options that employers would be expected to select only if those options did not impose any net cost burdens on them, the rule will not have a significant impact on a substantial number of small entities.

OSHA received several comments in response to the NPRM related to the time savings anticipated by the proposal. As discussed in the ''Summary and Explanation,'' a number of commenters noted that time savings of the proposed fit testing protocols would increase efficiency and be substantial when aggregated across a large number of employees (OSHA–2015–0015–0018, OSHA–2015–0015–0020). No comments indicated that the time savings estimates would be significantly different from those put forth in the Preliminary Economic Analysis (PEA).[13] As a result, OSHA has not changed its methodology for calculating the potential cost savings of implementing the new protocols.

The new quantitative fit testing (QNFT) protocols will provide employers additional options to fit test their employees for respirator use. While OSHA approves fit testing protocols rather than fit testing machines, OSHA understands that, currently, the market for fit testing machines using the original ambient aerosol CNC protocol is dominated by TSI's PortaCount® machines (Models 8020, 8030, 8038, 8040, 8048).[14] As such, OSHA's Final Economic Analysis (FEA) focuses specifically on TSI's PortaCount® machines. Employers already using the original ambient aerosol CNC protocol with a PortaCount® machine (with the exception of the now-discontinued 8020) may switch from the original ambient aerosol CNC protocol to the new protocols. OSHA estimates switching saves approximately 5 minutes per fit test, and grants the employer corresponding cost savings.

According to TSI, ''[e]xisting owners of the PortaCount® Respirator Fit Tester Pro Model 8030 and/or PortaCount® Pro+ Model 8038 will be able to utilize the new protocols without additional expense. It will be necessary for fit testers to obtain a firmware and FitPro software upgrade, which TSI will be providing as a free download. As an alternative to the free download, PortaCount® Models 8030 and 8038 returned for annual service will be upgraded without additional charge. Owners of the PortaCount® Plus Model 8020 with or without the N95-Companion™ Technology (both discontinued in 2008) will be limited to the current 8-exercise OSHA fit test protocol'' (OSHA–2015–0015–0010).[15] There are approximately 12,000 Model 8030 or 8038 units in the field.[16] Existing PortaCount® users may adopt the new protocols with minimal effort: The fit tester will be able to select the new protocol after taking an estimated less than five minutes to download TSI's firmware and software updates. The individual being fit tested is also likely to learn the new protocols with minimal time. In fact, information about the new protocols could be imparted during the annual training mandated by OSHA's respiratory protection rule (OSHA–2015–0015–0012). As a practical matter, the new protocols contain fewer exercises requiring mastery. And Part I.A.12 of appendix A of OSHA's Respiratory Protection Standard already requires the fit tester to describe the fit test to the respirator wearer, regardless of which fit test it is or how often it is used. Thus, there should be no additional burden to the employer or employee.

OSHA anticipates many employers who currently use the original ambient aerosol CNC protocol will adopt the new protocols because they could be adopted at negligible cost to the employer and would take less time to administer. OSHA expects that the new protocols are less likely to be adopted by employers who currently perform fit testing using other quantitative or qualitative fit tests because of the significant equipment and training investment that they already have made to administer these fit tests. For example, OSHA estimates, based on information from TSI, that switching from qualitative to quantitative fit testing would require upfront costs of $8,700 to $12,000 per machine (OSHA–2015–0015–0012).

OSHA has estimates of the number of users of the PortaCount® technology at the establishment level, both from the manufacturer and from the 2001 NIOSH Respirator Survey. However, what is not known is how many respirator wearers, that is, employees, are fit tested using a PortaCount® device. As described in the PEA, OSHA expects that economies of scale will apply in this situation—larger establishments will be more likely to encounter situations needing QNFT, but will also have more employees over which to spread the capital costs. OSHA received no comments about its understanding of employer size in relation to QNFT use. Once employers have invested capital in a quantitative fit testing device, they have more of an incentive to perform QNFT in a given situation, even if not technically required to use QNFT in every situation. Also, some QNFT devices are acquired by third parties, or ''fit testing houses,'' that provide fit testing services to employers. In short, as put forth in the PEA, OSHA believes that employers using PortaCount® QNFT will process more respirator wearers than the average establishment. OSHA received no comments about this conclusion.

As set forth in the PEA, if one started with an estimate of 12,000 establishments using PortaCount®

[13] As discussed in the ''Summary and Explanation,'' several comments (OSHA–2015–0015–0022, OSHA–2015–0015–0032, OSHA–2015–0015–0042) expressed concern about the estimated decrease in total ambient test time included as part of the protocol. The ''Summary and Explanation'' explains why this test time is reasonable and sufficient in this context. However, the comments did not question the total estimated time savings for the new protocols, per se.

[14] TSI indicated that as of the beginning of 2018, there were no active competitors, but that at least one company may be entering the market later in the year (OSHA–2015–0015–0046).

[15] TSI later confirmed this information still applied in 2018, even after the introduction of their new models (OSHA–2015–0015–0046).

[16] As indicated by TSI in 2015 (OSHA–2015–0015–0012). As explained later on in this FEA, the aggregate cost savings were based on estimates of current use of the 8030 and 8038 models. As the market is now being augmented with the 8040 and 8048 models, it is likely a conservative estimate of the potential cost savings.

models 8030 and 8038 annually for all of their employees and assumed an average of 100 respirator wearers fit tested annually per establishment, this yielded an estimate of 1.2 million respirator wearers that could potentially benefit from the new QNFT protocols.[17] Alternatively, as also set out in the PEA, a similar estimate would have been obtained if one assumed, employing data from the 2001 NIOSH Respirator Survey, that 50 percent of the devices requiring QNFT (such as full-facepiece elastomeric negative pressure respirators) use PortaCount® currently, as well as 25 percent of half-mask elastomeric respirators, and 10 percent of filtering facepieces.[18] These estimates in the PEA were not questioned in public comment. In the intervening period between the PEA and the FEA, the total number of employees and estimated respirator wearers increased somewhat, raising the estimated number of respirator wearers affected by the rulemaking, based on survey data, to approximately 1.3 million.

If applied to approximately 1.3 million respirators wearers, an estimated savings of 5 minutes per respirator wearer would equal over 100,000 hours of employee time saved annually. Consistent with Department of Labor policy for translating the labor time savings into dollar cost savings for this FEA, OSHA included an overhead rate when estimating the marginal cost of labor in its primary cost calculation. Overhead costs are indirect expenses that cannot be tied to producing a specific product or service. Common examples include rent, utilities, and office equipment. Unfortunately, there is no general consensus on the cost elements that fit this definition. The lack of a common definition has led to a wide range of overhead estimates. Consequently, the treatment of overhead costs needs to be case-specific. OSHA adopted an overhead rate of 17 percent of base wages, consistent with overhead rates used for other regulatory compliance rules.[19] For example, this is consistent with the overhead rate used for sensitivity analyses in the 2017 Improved Tracking FEA and the FEA in support of OSHA's 2016 final standard on Occupational Exposure to Respirable Crystalline Silica. For example, in this case, to calculate the total labor cost for a typical respirator wearer, based on the mean worker wage, three components are added together: Base wage ($23.86) + fringe benefits ($10.42—43.7% of $23.86);[20] and the applicable overhead costs ($4.06—17% of $23.86). This results in an hourly labor cost of a respirator wearing employee to $38.34. This implies an estimated cost savings of $4.1 million attributable to the adoption of the new fit testing protocols.

Because the $4.1 million represents annual cost savings, the final estimate is the same when discounted at either 3 or 7 percent. For the same reason, when the Department of Labor uses a perpetual time horizon to allow for cost comparisons under E.O. 13771, the annualized cost savings of the final rule are also $4.1 million with 7 percent discounting. As indicated earlier, this final estimate includes an overhead factor in the labor costs. This is estimated to add an additional savings of approximately 12%, or over $400,000, on what would have been an estimated savings of $3.6 million.

In addition to costs related to the respirator wearer's time, there will also likely be time savings for the person administering the fit tests. However, OSHA did not include this cost savings element in the PEA because it lacked specific empirical information on this point at the time of the proposal. OSHA requested comment on this question, but did not receive any. While OSHA believes this element of the cost savings is potentially substantial, it is not a critical element for the FEA, as it is simply a question of how large the cost savings are, and not required, for example, to determine economic feasibility. Therefore, OSHA is maintaining in the final analysis the same analytical approach used in the PEA.[21]

In addition, as discussed, this FEA does not account for potential conversions from testing methods other than the original ambient aerosol CNC protocol. While such conversions could further increase time and cost savings, OSHA cannot predict the number of conversions with confidence. In short, while certain factors could change the precise cost savings estimates in the FEA, OSHA believes its estimates reasonably capture the direction and order of magnitude of the rulemaking's economic effects.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (as amended), OSHA has examined the regulatory requirements of the final rule to determine whether these requirements will have a significant economic impact on a substantial number of small entities. This rule will impose no required costs and could provide a cost savings in excess of $4 million per year to regulated entities. While measureable in the aggregate, these savings will be dispersed widely, and therefore are not estimated to have a substantial economic impact on any small entity, although the impacts are estimated to be positive. The Assistant Secretary for Occupational Safety and Health therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

Overview

The Paperwork Reduction Act (PRA) requires that agencies obtain approval from OMB before conducting any collection of information (44 U.S.C. 3507). The PRA defines ''collection of information'' to mean ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format'' (44 U.S.C. 3502(3)(A)).

In accordance with the PRA, 44 U.S.C. 3506(c)(2), OSHA solicited public comments on proposed revisions to the Respiratory Protection Standard Information Collection Request (ICR) (paperwork burden hour and cost

[17] TSI estimated the number of users of their devices at over 12,000 establishments (OSHA–2015–0015–0012). As indicated in the PEA, this was consistent with data from the 2001 NIOSH respirator survey (OSHA–2015–0015–0045), which, if benchmarked to a 2012 count of establishments (OSHA–2015–0015–0048) and containing fit testing methods to include ambient aerosol, generated aerosol, and a proportionally allocated percentage of the ''don't know'' respondents, would provide an estimate of 12,458 establishments using PortaCount® currently. Based on information from TSI, the large majority of these are estimated to be the newer 8030 and 8038 devices.

[18] Based on the 2001 NIOSH respirator survey (OSHA–2015–0015–0045), benchmarked to 2015 County Business Patterns (OSHA–2015–0015–0048), OSHA estimates 1,273,616 (or approximately 1.3 million) employees will be affected by the rulemaking. These estimates are based only on private employers. Accounting for governmental entities would result in an even larger number of total estimated respirator users affected.

[19] The methodology was modeled after an approach used by the Environmental Protection Agency. More information on this approach can be found at: U.S. Environmental Protection Agency, ''Wage Rates for Economic Analyses of the Toxics Release Inventory Program,'' June 10, 2002. This analysis itself was based on a survey of several large chemical manufacturing plants: Heiden Associates, *Final Report: A Study of Industry Compliance Costs Under the Final Comprehensive Assessment Information Rule,* Prepared for the Chemical Manufacturers Association, December 14, 1989.

[20] Mean wage rate of $23.86 (OSHA–2015–0015–0043), assuming fringe benefits are 30.4 percent of total compensation (OSHA–2015–0015–0043), or by extension, 43.7% of base wages (1/(1–bw)).

[21] For example, in the PEA OSHA posited that the time saved may potentially be as much as a 1:1 ratio between the tester and those being tested. But, for purposes of argument, if the ratio was only 1:4 (or the equivalent of 1 minute 15 seconds of tester's time per employee tested), OSHA estimates the cost savings related to the tester would be an additional $1.3 million.

analysis) for the information collection requirements associated with the *Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard* proposed rule (81 FR 69747). The Department submitted this ICR to OMB for review in accordance with 44 U.S.C. 3507(d) on October 7, 2016. A copy of the ICR for the proposed rule is available to the public at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201511-1218-005.*

Solicitation of Comments

On November 22, 2016, OMB issued a Notice of Action withholding its approval of the ICR. OMB requested that, ''[p]rior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates.''

No public comments were received specifically in response to the proposed ICR submitted to OMB for review. However, several public comments submitted in response to the NPRM, described earlier in this preamble, substantively addressed provisions containing collections of information and included information relevant to the burden hour and costs analysis. These comments are addressed in the preamble, and OSHA considered them when it developed the revised ICR associated with this final rule. See the comment analysis in section II.D above.

Under the PRA, a Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and the collection of information notice displays a currently valid OMB control number (44 U.S.C. 3507(a)(3)). Also, notwithstanding any other provision of law, no employer shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512). The revised information collection requirements found in the final rule are summarized below.

The Department of Labor has submitted the final ICR concurrent with the publication of this final rule. The ICR contains a full analysis and description of the burden hours and costs associated with the information collection requirements of the final rule to OMB for approval. A copy of the ICR is available to the public at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201904-1218-002.* OSHA will publish a separate notice in the **Federal Register** announcing the results of OMB's review. That notice will also include a list of OMB-approved information collection requirements and the total burden hours and costs imposed by the final rule.

The additional protocols adopted in this final rule revise the information collection in a way that reduces existing burden hours and costs. In particular, the information collection requirement specified in paragraph (m)(2) of OSHA's Respiratory Protection Standard, at 29 CFR 1910.134, states 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 test results. The employer must maintain this record until the next fit test is administered. While the information on the fit test record remains the same, the time to obtain the necessary information for the fit test record is reduced since the additional PortaCount® protocols will take an employer less time to administer than those currently approved in appendix A of the Respiratory Protection Standard. As a result, the total estimated burden hours decrease by 201,640 hours, from 7,622,100 to 7,420,460 hours. This decrease is a result of the more efficient protocols established under the final rule. OSHA accounts for this burden under the Information Collection Request, or paperwork analysis, for the Respiratory Protection Standard (OMB Control Number 1218–0099). Note that OSHA cannot require compliance with the information collection requirements for the new information collection in this final rule until OMB has approved the information collection requirements.

Title of Collection: Respiratory Protection Standard (29 CFR1910.134).

OMB Control Number: 1218–0099.

Affected Public: Private Sector—business or other for-profits.

Total Estimated Number of Respondents: 24,710,469.

Total Estimated Number of Responses: 25,042,236.

Total Estimated Annual Time Burden Hours: 7,420,460.

Total Estimated Annual Other Burden: $316,906,665.

D. Federalism

OSHA reviewed this rulemaking according to the Executive Order on Federalism (E.O. 13132, 64 FR 43255, Aug. 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states before taking actions that would restrict states' policy options and take such actions only when clear constitutional authority exists and the problem is of national scope. The Executive Order provides for preemption of state law only with the expressed consent of Congress. Federal agencies must limit any such preemption to the extent possible.

Under section 18 of the Occupational Safety and Health Act (the ''Act,'' 29 U.S.C. 651 *et seq.*), Congress expressly provides that states may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards (29 U.S.C. 667). OSHA refers to states that obtain Federal approval for such a plan as ''State Plan states.'' Occupational safety and health standards developed by State Plan states must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State Plan states are free to develop and enforce under state law their own requirements for occupational safety and health standards. With respect to states that do not have OSHA-approved plans, OSHA concludes that this standard conforms to the preemption provisions of the Act. Section 18 of the Act prohibits states without approved plans from issuing citations for violations of OSHA standards. OSHA finds that the rule does not expand this limitation. Therefore, for States that do not have approved occupational safety and health plans, the rule will not affect the preemption provisions of Section 18 of the Act.

OSHA's rulemaking to adopt additional fit testing protocols under its Respiratory Protection Standard at 29 CFR 1910.134 is consistent with Executive Order 13132 because the problems addressed by these fit testing requirements are national in scope. OSHA concludes that the fit testing protocols adopted by this rulemaking provide employers in every state with procedures that will assist them in protecting their employees from the risks of exposure to atmospheric hazards. In this regard, the rule offers thousands of employers across the nation an opportunity to use additional protocols to assess respirator fit among their employees. Therefore, the rule provides employers in every state with an alternative means of complying with the fit testing requirements specified by paragraph (f) of OSHA's Respiratory Protection Standard.

Section 18(c)(2) of the Act (29 U.S.C. 667(c)(2)) requires State Plan states to

adopt an OSHA standard, or to develop and enforce an alternative that is at least as effective as the OSHA standard. However, the new fit testing protocols adopted by this rulemaking provide employers with alternatives to the existing fit testing protocols specified in the Respiratory Protection Standard; therefore, the alternative is not, itself, a mandatory standard. Accordingly, states with OSHA-approved State Plans are not obligated to adopt the additional fit testing protocols adopted here. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide additional compliance options to employers in their states.

In summary, this rulemaking complies with Executive Order 13132. In states without OSHA-approved State Plans, this rulemaking limits state policy options in the same manner as other OSHA standards. In State Plan states, this rulemaking does not significantly limit state policy options.

E. State Plan States

Section 18(c)(2) of the Act (29 U.S.C. 667(c)(2)) requires State Plan states to adopt mandatory standards promulgated by OSHA, or to develop and enforce an alternative that is at least as effective as the OSHA standard. However, as noted in the previous section of this preamble, states with OSHA-approved State Plans are not obligated to adopt the provisions of this final rule. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide compliance options to employers in their States. In this regard, OSHA concludes that the fit testing protocols adopted by this rulemaking provide employers in the State Plan states with procedures that protect the safety and health of employees who use respirators against hazardous airborne substances in their workplace at least as well as the quantitative fit testing protocols in appendix A of the Respiratory Protection Standard.

There are 28 states and U.S. territories that have their own OSHA-approved occupational safety and health programs called State Plans. The following 22 State Plans cover state and local government employers and private-sector employers: 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. The following six State Plans cover state and local government employers only: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

F. Unfunded Mandates Reform Act

OSHA reviewed this rulemaking according to the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501–1507) and Executive Order 12875 (58 FR 58093 (1993)). As discussed above in section III.B of this preamble (''Final Economic Analysis and Regulatory Flexibility Certification''), OSHA has determined that the rule imposes no additional costs on any private-sector or public-sector entity. The substantive content of the rule applies only to employers whose employees use respirators for protection against airborne contaminants, and compliance with the protocols contained in the final rule are strictly optional for these employers. Accordingly, the final rule does not require additional expenditures by either public or private employers. Therefore, this rulemaking is not a significant regulatory action within the meaning of Section 202 of the UMRA, 2 U.S.C. 1532.

As noted above under Section E (''State Plan States'') of this preamble, OSHA standards do not apply to state or local governments except in states that have voluntarily elected to adopt an OSHA-approved State Plan. Consequently, this final rulemaking does not meet the definition of a ''Federal intergovernmental mandate'' (see 2 U.S.C. 658(5)). Therefore, for the purposes of the UMRA, the Assistant Secretary for Occupational Safety and Health certifies that this rulemaking does not mandate that state, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

G. Applicability of Existing Consensus Standards

Section 6(b)(8) of the Act (29 U.S.C. 655(b)(8)) requires OSHA to explain ''why a rule promulgated by the Secretary differs substantially from an existing national consensus standard,'' by publishing ''a statement of the reasons why the rule as adopted will better effectuate the purposes of the Act than the national consensus standard.'' The American National Standards Institute (ANSI) developed a national consensus standard on fit testing protocols (''Respirator Fit Testing Methods,'' ANSI Z88.10–2001) as an adjunct to its national consensus standard on respiratory protection programs. ANSI/AIHA updated the Z88.10 standard in 2010 (''Respirator Fit Testing Methods,'' ANSI Z88.10–2010) (OSHA–2015–0015–0007).

Paragraph 7.2 of ANSI/AIHA Z88.10–2010 specifies the requirements for conducting a particle-counting-instrument (*e.g.,* PortaCount®) quantitative fit test. The modified CNC protocols adopted by the final rule are variations of this national consensus standard's particle counting-instrument quantitative fit test procedures: The new protocols require the same 30-second duration for fit testing exercises, but not the same exercises as ANSI/AIHA. However, Annex A2 of ANSI/AIHA Z88.10–2010 recognizes that a universally accepted measurement standard for respirator fit testing does not exist and provides specific requirements for evaluating new fit testing methods. OSHA has concluded that the modified CNC protocols submitted by TSI meet the evaluation criteria outlined in ANSI/AIHA Z88.10–2010, Annex A2.

H. Advisory Committee for Construction Safety and Health (ACCSH) Review of the Proposed Standard

The Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 3704), OSHA regulations governing the Advisory Committee for Construction Safety and Health (ACCSH) (*i.e.,* 29 CFR 1912.3), and provisions governing OSHA rulemaking (*i.e.,* 29 CFR 1911.10) require OSHA to consult with the ACCSH whenever OSHA proposes a rule involving construction activities. Specifically, 29 CFR 1911.10 requires that the Assistant Secretary provide the ACCSH with ''any proposal of his own,'' together with ''all pertinent factual information available to him, including the results of research, demonstrations, and experiments.''

The addition of two quantitative fit test protocols to appendix A of OSHA's Respiratory Protection Standard affects the construction industry because it revises the fit testing procedures used in that industry (see 29 CFR 1926.103). Accordingly, OSHA provided the ACCSH members with TSI's application letter, supporting documents, and other relevant information, prior to the December 4, 2014 ACCSH meeting. OSHA explained its proposal to add new protocols to the ACCSH at that meeting, and the ACCSH unanimously approved proceeding with a proposed rule.

List of Subjects in 29 CFR Part 1910

Fit testing, Hazardous substances, Health, Occupational safety and health, Respirators, Respiratory protection, Toxic substances.

Authority and Signature

Loren Sweatt, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this document pursuant to Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 1–2012 (77 FR 3912).

Signed at Washington, DC, on September 19, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

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: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 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), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable, and 29 CFR part 1911.

■ 2. Amend Part I in appendix A to § 1910.134 as follows:
■ a. Revise Section A.14(a) introductory text;
■ b. In Section C.3:
■ i. Revise the introductory text; and
■ ii. Remove the terms ''Portacount™'' and ''Portacount'' and add in their place the term ''PortaCount®'';
■ c. Redesignate Sections C.4 and 5 of as Sections C.6 and 7;
■ d. Add new Sections C.4 and 5; and
■ e. In newly redesignated Section C.7:
■ i. Revise paragraph (a) and paragraph (b) introductory text; and
■ ii. Redesignate Table A–1 as Table A–3; and

The revisions and additions read as follows:

§ 1910.134 Respiratory protection.

* * * * *

APPENDIX A to § 1910.134—FIT TESTING PROCEDURES (MANDATORY)

Part I. OSHA—Accepted Fit Test 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 two modified ambient aerosol CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified ambient aerosol CNC quantitative fit testing protocols, employers shall ensure that the test subjects (*i.e.,* employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for full-facepiece and half-mask elastomeric respirators, or the exercise procedure specified in Part I.C.5(b) for filtering facepiece respirators. Employers shall ensure that the test subjects (*i.e.,* employees) perform the exercise procedure specified in Part I.C.6(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.7(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

* * * * *

C. Quantitative Fit Test (QNFT) Protocols

* * * * *

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount®) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The primary CNC instrument manufacturer, TSI Incorporated, also provides probe attachments (TSI mask sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator (elastomeric or filtering facepiece), and a minimum fit factor pass level of at least 500 is required for a full-facepiece elastomeric respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

* * * * *

4. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

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

TABLE A–1— MODIFIED AMBIENT AEROSAL CNC QUANTITATIVE FIT TESTING PROTOCOL FOR FULL FACEPIECE AND HALF–MASK ELASTOMERIC RESPIRATORS

Exercises [1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom [2].	A 20 second ambient sample, followed by a 30 second mask sample.
Jogging-in-Place	The test subject shall jog in place comfortably for 30 seconds	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme [2].	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme [2].	A 30 second mask sample followed by a 9 second ambient sample.

[1] Exercises are listed in the order in which they are to be administered.
[2] It is optional for test subjects to take additional breaths at other times during this exercise.

5. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–2 of this appendix.

TABLE A–2— MODIFIED AMBIENT AEROSAL CNC QUANTITATIVE FIT TESTING PROTOCOL FOR FILTERING FACEPIECE RESPIRATORS

Exercises [1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom [2].	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme [2].	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme [2].	A 30 second mask sample followed by a 9 second ambient sample.

[1] Exercises are listed in the order in which they are to be administered.
[2] It is optional for test subjects to take additional breaths at other times during this exercise.

* * * * *

7. 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.6 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.6 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 in Table A–3 of this appendix.

* * * * *

[FR Doc. 2019–20686 Filed 9–25–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0756]

RIN 1625–AA00

Safety Zone, Wilmington River, Savannah, GA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Wilmington River 1,000 feet on the north and south side of the Islands Expressway Bridge in Savannah, GA. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by the placement of multiple spans for the new Islands Expressway Bridge. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Savannah or a designated representative.

DATES: This rule is effective without actual notice from September 26, 2019 to 2:00 p.m. on October 22, 2019. For the purposes of enforcement, actual notice will be used from 8:00 a.m. on September 18, 2019 through September 26, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0756 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Rachel Crowe, Marine Safety Unit Savannah Office of Waterways Management, Coast Guard; telephone 912–652–4353, extension 243, or email *Rachel.M.Crowe@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. Immediate action is needed to respond to the potential safety hazards created by the placement of multiple spans for the new Islands Expressway Bridge. The Coast Guard received information on August 27, 2019 regarding the operations beginning on September 18, 2019. The operation would begin before the rulemaking process would be completed. Because of the dangers posed by the placement of multiple spans, the safety zone is necessary to provide for the safety of persons, vessels, and the marine environment in the event area.

Under 5 U.S.C. 553(d)(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 of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the construction and placement of multiple spans.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The COTP Savannah has determined that potential hazards associated with the placement of multiple spans for the new Islands Expressway Bridge starting September 18, 2019, will be a safety concern for anyone within 1,000 feet of the north and south side of the Islands Expressway Bridge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during bridge construction.

IV. Discussion of the Rule

This rule establishes a safety zone from 8:00 a.m. on September 18, 2019