DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2016–C–2767]

Wm. Wrigley Jr. Company; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Wm. Wrigley Jr. Company, proposing that the color additive regulations be amended to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum.

DATES: The color additive petition was filed on September 1, 2016.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1282.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 6C0307), submitted by Wm. Wrigley Jr. Company, c/o Exponent, 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in part 73 (21 CFR part 73) *Listing of Color Additives Exempt From Certification,* to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum.

We have determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: October 3, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–24208 Filed 10–6–16; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2015–0015]

RIN 1218–AC94

Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard

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

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: OSHA is proposing to add two modified PortaCount® quantitative fit-testing protocols to its Respiratory Protection Standard. The proposed protocols would apply to employers in general industry, shipyard employment, and the construction industry. Both proposed protocols are variations of the existing OSHA-accepted PortaCount® protocol, but differ from it by the exercise sets, exercise duration, and sampling sequence. If approved, the modified PortaCount® protocols would be alternatives to the existing quantitative fit-testing protocols already listed in an appendix of the Respiratory Protection Standard. In addition, OSHA is proposing to amend an appendix to clarify that PortaCount® fit test devices equipped with the N95-Companion™ Technology are covered by the approved PortaCount® protocols.

DATES: Submit comments to this proposal, including comments to the information collection (paperwork) requirements, by December 6, 2016.

ADDRESSES: *Written comments.* You may submit comments, identified by Docket No. OSHA–2015–0015, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov*, which is the Federal e-Rulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: You must submit your comments to the OSHA Docket Office, Docket No. OSHA–2015–0015, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Deliveries (hand, express mail, messenger, or courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., ET.

Instructions: All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA–2015–0015). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but does not require) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (*e.g.*, consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific and technical analyses, OSHA requests (but does not require) that you disclose: (1) The nature of any financial relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party prior to its submission. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

Docket: To read or download comments and materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA–2015–0015 at *http://www.regulations.gov* or to the OSHA Docket Office at the address above. All comments and submissions are listed in the *http://*

www.regulations.gov index; however, some information (*e.g.*, copyrighted material) is not publicly available to read or download through that Web site. All comments and submissions are available for inspection and, where permissible, copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://regulations.gov.* Copies also are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1888. This document, as well as news releases and other relevant information, is also available at OSHA's Web site at *http://www.osha.gov.*

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Frank Meilinger, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *Meilinger.francis2@dol.gov.* For technical inquiries, contact Natalia Stakhiv, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2272; email *stakhiv.natalia@dol.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

Appendix A of OSHA's Respiratory Protection Standard, 29 CFR 1910.134, currently includes four quantitative fit-testing protocols using the following challenge agents: A non-hazardous generated aerosol such as corn oil, polyethylene glycol 400, di-2-ethyl hexyl sebacate, or sodium chloride; ambient aerosol measured with a condensation nuclei counter (CNC), also known as the standard PortaCount® protocol; controlled negative pressure; and controlled negative pressure REDON. Appendix A of the Respiratory Protection Standard also specifies the procedure for adding new fit-testing protocols to this standard. Under that procedure, if OSHA receives an application for a new fit-testing protocol meeting certain criteria, the Agency must commence a rulemaking proceeding to consider adopting the proposal. These criteria include: (1) A test report prepared by an independent government research laboratory (*e.g.*, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory tested the protocol and found it to be accurate and reliable; or (2) an article published in a peer-reviewed industrial-hygiene journal describing the protocol and explaining how the test data support the protocol's accuracy and reliability. 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)). Using this procedure, OSHA added one fit-testing protocol (*i.e.*, the controlled negative pressure REDON quantitative fit-testing protocol) to appendix A of its Respiratory Protection Standard (69 FR 46986, Aug. 4, 2004).

In 2006, TSI Incorporated (hereinafter referred to as TSI) submitted two quantitative fit-testing protocols for acceptance under the Respiratory Protection Standard. OSHA published a notice of proposed rulemaking (NPRM) for those protocols on January 21, 2009 (74 FR 3526–01). The proposed protocols used the same fit-testing requirements and instrumentation specified for the standard PortaCount® protocol in paragraphs (a) and (b) of Part I.C.3 of appendix A of the Respiratory Protection Standard, except:

- Revised PortaCount® QNFT protocol 1 reduced the duration of the eight fit-testing exercises from 60 seconds to 30 seconds; and
- Revised PortaCount® QNFT protocol 2 eliminated two of the eight fit-testing exercises, with each of the remaining six exercises having a duration of 40 seconds; in addition, this proposed protocol increased the minimum pass-fail fit-testing criterion (*i.e.*, reference fit factors) from a fit factor of 100 to 200 for half masks, and from 500 to 1000 for full facepieces.

OSHA withdrew the NPRM on January 27, 2010 (75 FR 4323–01). In withdrawing the NPRM, the Agency concluded that the study data failed to adequately demonstrate that these protocols were sufficiently accurate or as reliable as the quantitative fit-testing protocols already listed in appendix A. OSHA found that the studies submitted with the application did not differentiate between results for half-mask and full-facepiece respirators. OSHA also determined that TSI had not demonstrated that these protocols would accurately determine fit for filtering facepiece respirators.

II. Summary and Explanation of the Proposal

A. Introduction

One of the OSHA-accepted quantitative fit test protocols listed in appendix A is the standard PortaCount® protocol. The standard PortaCount® protocol and instrumentation was introduced by TSI in 1987, and the use of the standard PortaCount® protocol was originally allowed by OSHA under a compliance interpretation published in 1988, until it was incorporated into appendix A in 1998.

In a letter dated July 10, 2014, Darrick Niccum of TSI submitted an application requesting that OSHA approve three additional PortaCount® quantitative fit test protocols to add to appendix A (TSI, 2014a). These three additional protocols are modified versions of the standard PortaCount® protocol. Mr. Niccum included a copy of three peer-reviewed articles from the industrial-hygiene journal, entitled *Journal of the International Society for Respiratory Protection*, describing the accuracy and reliability of these proposed protocols (Richardson et al., 2013; Richardson et al., 2014a; Richardson et al., 2014b). The application letter also included a copy of the ANSI/AIHA Z88.10–2010 standard (ANSI/AIHA, 2010) and a discussion about how the ANSI/AIHA Z88.10–2010, Annex 2 methodology was utilized by TSI to conduct a statistical comparison of fit test methods.

For consistency with the terminology used in the three peer-reviewed articles, OSHA will, in this section of the NPRM (*i.e.*, Summary and Explanation of the Proposal), refer to the three new modified PortaCount® protocols as ''Fast-Full method'' for full-facepiece elastomeric respirators, ''Fast-Half method'' for half-mask elastomeric respirators, and ''Fast-FFR method'' for filtering-facepiece respirators (FFR). It should be noted that the ''Fast-Full'' method and the ''Fast-Half'' method are identical protocols, but were evaluated for method performance separately in two peer-reviewed articles. Since TSI's ''Fast-Full'' and ''Fast-Half'' methods are identical protocols, OSHA is proposing that only two new protocols be added to appendix A: A modified PortaCount® protocol for *both* full-facepiece and half-mask elastomeric respirators and a modified PortaCount® protocol for filtering-facepiece respirators.

All three of TSI's modified PortaCount® protocols use the same fit-testing requirements and instrumentation specified for the standard PortaCount® protocol in paragraphs (a) and (b) of Part I.C.3 of

appendix A of the Respiratory Protection Standard, except that they differ from the standard PortaCount® protocol by the exercise sets, exercise duration, and sampling sequence. The major difference between the proposed Fast-Full and Fast-Half methods and the standard PortaCount® protocol is they include only 3 of the 7 current test exercises (*i.e.*, bending, head side-to-side, and head up-and-down) plus a new exercise (*i.e.*, jogging-in-place), and reduce each exercise duration, thereby reducing the total test duration from 7.2 minutes to 2.5 minutes. The peer-reviewed articles describe studies comparing the fit factors for the new modified PortaCount® protocols to a reference method based on the American National Standards Institute (ANSI/AIHA) Z88.10–2010 Annex A2 ''Criteria for Evaluating New Fit Test Methods'' approach. This approach requires the performance evaluation study administer sequential paired tests using the proposed fit-test method and reference method during the same respirator donning.

B. Evaluation of Fast-Half Method

1. Study Methods

The peer-reviewed article entitled ''Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount®,'' appeared in a 2014 issue (Volume 31, Number 1) of the *Journal of the International Society for Respiratory Protection* (Richardson et al., 2014a). The study authors selected three models of NIOSH-approved, half-mask 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 flush sampling probe located between the nose and mouth. Twenty-five participants (9 female; 16 male) were included in the study; face sizes were predominantly in the smaller and central cells (1, 2, 3, 4, 5, 7, 8) of the NIOSH bivariate panel; no subjects were in cells 6, 9 or 10 (those with longer—nose to chin—face sizes).

Test subjects donned the respirator for a five-minute comfort assessment and then performed two sets of fit-test exercises, either using the Reference method or the Fast-Half method. The order of the two sets of fit-test exercises was randomized. 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 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.

According to TSI, the study authors chose not to include the grimace exercise because little or no support was found for the grimace exercise among respirator fit-test experts (TSI, 2015a). TSI explained that ''[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 (TSI, 2015a).'' They further commented that the grimace is intended to break the face seal and may not reseal in the same way for subsequent exercises. As a result, the shift in the respirator can potentially confound comparison of the fit-test methods. TSI also noted that the fit factor from the grimace (if measured) is not used to calculate the overall fit factor test result under the standard PortaCount® method (TSI, 2015a).

The Fast-Half method included four exercises—bending, jogging in place, head side-to-side and head up-and-down. Two breaths were taken 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 peer-reviewed journal article, TSI explained their rationale for selecting the exercises that were the most rigorous for (*i.e.*, the best at) identifying poor fitting respirators in two documents submitted to the Agency (TSI, 2014b; TSI, 2015a). TSI selected the exercises based on a literature review, informal conversations with industry fit test experts, and in-house pilot studies. ''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. (Zhuang et al., 2004). TSI's in-house pilot collected fit-test data on subjects using consecutive sets of the seven-exercise Reference method described above (TSI, 2014b). TSI analyzed the frequency with which each exercise produced the lowest fit factor. Fit test data was 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. The 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 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 that most often had the lowest fit factor for good-fitting full-facepiece and half-mask respirators in the 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 (TSI, 2015a). The study added jogging-in-place for a fourth rigorous test exercise as part of the protocol. Jogging is an alternate (*i.e.*, elective as opposed to required) exercise in Annex 2—''Criteria for Evaluating New Fit Test Methods of the Respiratory Protection'' of the ANSI/AIHA Z88.10–2010 standard.

A single CPC instrument, PortaCount® Model 8030 (TSI Incorporated, Shoreview MN), was used throughout the Fast-Half method validation experiments. The instrument was connected to two equal-length sampling tubes for sampling inside-facepiece and ambient particle concentrations. TSI software was used to switch between sampling lines and record concentration data. The experiments were conducted in a large chamber to which a NaCl aerosol was added to augment particle concentrations, which were expected to range between 5,000 and 20,000 particles/cm^3 (target = 10,000 p/cm^3).

During the Reference method, for each exercise, the ambient sampling tube was first purged for 4 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.

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 5 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 Reference method, the authors calculated a fit factor for each exercise by dividing the in-facepiece

concentration taken during that exercise by the mean ambient concentration for that exercise (average of the ambient measurements pre- and post-exercise). The overall fit factor was determined by taking a harmonic mean of the seven exercise fit factors.

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.

2. Study Results

The ANSI/AIHA standard 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 which cannot be confirmed to be greater than 100 or less than 100 with adequate confidence and, therefore, should not be included in evaluating performance. TSI determined the variability associated with the Reference method using 48 pairs of fit factors from 16 participants. The exclusion zone was defined as fit factor measurements within one standard deviation of the 100 pass/fail value. Six pairs of fit factors were omitted 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 82–123 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 (Brosseau and Jones, 2015). The recalculated exclusion zone was somewhat wider, ranging from 68 to 146.

The final dataset for the ANSI/AIHA Fast-Half performance evaluation included 134 pairs of fit factors from 25 participants. Equivalent fractions of each respirator and model were included. Eleven pairs were omitted because the ratio of maximum to minimum normal breathing fit factors was greater than 100 and 1 pair was omitted due to a methodological error; 122 pairs were included in the data analysis.

According to the statistical procedures utilized in the study, the Fast-Half method, even utilizing the wider OSHA-recalculated exclusion zone, met the required acceptance criteria for test sensitivity, predictive value of a pass, predictive value of a fail, test specificity, and kappa statistic [1] as defined in ANSI/AIHA Z88.10–2010 (see Table 1). The study authors concluded that the results demonstrated that the new Fast-Half method can identify poorly fitting respirators as well as the reference method.

C. Evaluation of Fast-Full Method

1. Study Methods

The peer-reviewed article entitled ''Evaluation of a Faster Fit Testing Method for Full-Facepiece Respirators Based on the TSI PortaCount®,'' appeared in a 2013 issue (Volume 30, Number 2) of the *Journal of the International Society for Respiratory Protection* (Richardson et al., 2013). 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 into the breathing zone. Twenty-seven participants (11 female; 16 male) were included in the study; face sizes were predominantly in the central cells (2, 3, 4, 5, 7, 8 and 9) of the NIOSH bivariate panel; 1 subject had a face size in cell 6 and none were in cells 1 (very small) or 10 (very large). The Reference method, choice of exercises, PortaCount® instrument, test aerosol, and sampling sequence were exactly the same as those used for the Fast-Half method. A minimum fit factor of 500 is required in order to be regarded as an acceptable fit for full-facepiece respirators under appendix A of the Respiratory Protection Standard.

2. Study Results

TSI 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 345–726 and did not include the three outliers. OSHA recalculated the exclusion zone with the outlier data included in the analysis (Brosseau and Jones, 2015). The recalculated exclusion zone determined by OSHA was somewhat wider ranging from 321–780.

The final dataset for the ANSI/AIHA Fast-Full performance evaluation included 148 pairs of fit factors from 27 participants. Equivalent fractions of each respirator and model were included. Eleven pairs were omitted because the ratio of maximum to minimum normal breathing fit factors was greater than 100; 1 pair was omitted due to an observational anomaly; 136 pairs were included in the data analysis.

According to the statistical procedures utilized in the study, the Fast-Full method, even utilizing the wider OSHA-recalculated exclusion zone, 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 ANSI/AIHA Z88.10–2010 (see Table 1). The authors concluded that the results demonstrated that the new Fast-Full method can identify poorly fitting respirators as well as the reference method.

D. Evaluation of Fast-FFR Method

1. Study Methods

The peer-reviewed article, entitled ''Evaluation of a Faster Fit Testing Method for Filtering Facepiece Respirators Based on the TSI PortaCount®,'' appeared in a 2014 issue (Volume 31, Number 1) of the *Journal of the International Society for Respiratory Protection* (Richardson et al., 2014b). Ten models of NIOSH-approved N95 FFRs from six ''leading U.S. mask manufacturers'' were selected for study. The different models were selected to

[1] 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.

represent a range of styles—6 cup-shaped, 2 horizontal flat-fold, and 2 vertical flat-fold models. No information was provided in the publication about whether models were available in different sizes. However, at the Agency's request, TSI submitted additional information regarding the choice of respirators via a letter (TSI, 2015b). The letter states:

> 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; face sizes were predominantly in the smaller and central cells (1, 2, 3, 4, 5, 7, 8) of the NIOSH bivariate panel; 1 subject was in cell 6 and no subjects were in cells 9 or 10 (those with longer—nose to chin—face sizes). 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 (TSI, 2015a). They felt from their own experience that jogging does not represent the kind of motions that FFR wearers do when using the respirator (TSI, 2015a). 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.

2. Study Results

The study administered sequential paired fit tests using the Fast-FFR method and a reference method according to the ANSI/AIHA standard. TSI determined the variability associated with the Reference method using 63 pairs of fit factors from 14 participants. The exclusion zone was defined as fit factor measurements within one standard deviation of the 500 pass/fail value. Two pairs of fit factors were omitted 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 78–128 and did not include the six outliers. OSHA recalculated the exclusion zone with the outlier data included in the analysis (Brosseau and Jones, 2015). The recalculated exclusion zone was somewhat wider ranging from 69–144.

The final dataset for the ANSI/AIHA Fast-FFR performance evaluation included 114 pairs from 29 participants. Equivalent fractions of each respirator and model were included. Two pairs were omitted because the ratio of maximum to minimum normal breathing fit factors was greater than 100; 112 pairs were included in the data analysis.

According to the statistical procedures utilized in the study, the Fast-FFR method, even utilizing the wider OSHA-recalculated exclusion zone, 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 ANSI/AIHA Z88.10–2010 (see Table 1). The authors concluded that the results demonstrated that the new Fast-FFR method can identify poorly fitting respirators as well as the reference method.

TABLE 1—COMPARISON OF TSI FIT TEST PROTOCOLS WITH ANSI CRITERIA

	ANSI Z88.10	Fast-full	Fast-half	Fast-FFR
Sensitivity	≥0.95	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 journal 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.

E. Conclusions

OSHA believes that the information submitted by TSI in the July 10, 2014 letter from Mr. Niccum in support of the modified PortaCount® quantitative fit test protocols meets the criteria for determining whether OSHA must publish fit-test protocols for notice-and-comment rulemaking established by the Agency in Part II of appendix A of its Respiratory Protection Standard. Therefore, the Agency is initiating this rulemaking to determine whether to approve these proposed protocols for inclusion in Part I.C of appendix A of its Respiratory Protection Standard.

Each proposed protocol is a variation of the standard OSHA-accepted PortaCount® protocol, but differs from it by the exercise sets, exercise duration, and sampling sequence. The major difference between the proposed Fast-Full and Fast-Half methods and the standard OSHA-accepted PortaCount® protocol is they include only 3 of the 7 current test exercises (*i.e.*, bending, head side-to-side, and head up-and-down) plus a new exercise (*i.e.*, jogging-in-place), and reduce the total test duration from 7.2 minutes to 2.5 minutes. The major difference between the proposed Fast-FFR method and the standard OSHA-accepted PortaCount® protocol is it includes 4 of the 7 current test exercises (*i.e.*, bending, talking, head side-to-side, and head up-and-down), and it reduces the total test

duration from 7.2 minutes to 2.5 minutes.

The Agency is proposing to add two modified PortaCount® protocols to appendix A (see section V of this preamble titled ''Proposed Amendment to the Standard''). If approved, the new protocols would be alternatives to the existing quantitative fit-testing protocols already listed in the Part I.C of appendix A of the Respiratory Protection Standard; employers would be free to select these alternatives or to continue using any of the other protocols currently listed in the appendix.

F. N95-Companion™ Technology

OSHA is also taking the opportunity of this rulemaking to make a clarifying change to appendix A of the Respiratory Protection Standard to reflect a technological development. The original PortaCount® model could only fit test elastomeric respirators (*i.e.*, full-facepiece and half-mask) and filtering facepiece respirators equipped with ≥99% efficient filter media. In 1998, TSI introduced the N95-Companion™ Technology, which enables newer PortaCount® models to quantitatively fit test elastomeric respirators (*i.e.*, full-facepiece and half-mask) and filtering facepiece respirators equipped with <99% efficient filter media (*e.g.*, N95 filters). The N95-Companion™ Technology does not alter the fit-testing protocol; it merely enables the fit testing of respirators with <99% efficient filter media. Therefore, OSHA has proposed text to appendix A, Part I.C.3 to clarify the difference between the existing PortaCount® models with and without the N95-Companion™ Technology.

III. Issues for Public Comment

OSHA invites comments from the public regarding 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. Specifically, the Agency invites public comment on the following issues:

- Were the three studies described in the peer-reviewed journal articles well controlled and conducted according to accepted experimental design practices and principles?
- Were the results of the three studies described in the peer-reviewed journal articles properly, fully, and fairly presented and interpreted?
- Did the three studies treat outliers appropriately in determination of the exclusion zone?
- Will the two proposed protocols generate reproducible fit-testing results?
- 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?
- 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?
- 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?
- 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?
- 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?
- 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?
- 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?
- Does OSHA's proposed regulatory text for the two new protocols offer clear instructions for implementing the protocols accurately?

IV. Procedural Determinations

A. Legal Authority

The purpose of the Occupational Safety and Health Act of 1970 (''the Act''; 29 U.S.C. 651 et seq.) is ''to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards (29 U.S.C. 655(b)).

Under the Act, a safety or health standard is a standard that ''requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment'' (29 U.S.C. 652(8)). A standard is reasonably necessary or appropriate within the meaning of section 652(8) of the Act when it substantially reduces or eliminates a significant workplace risk, and is technologically and economically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency action, and supported by substantial evidence; it also must effectuate the Act's purposes better than any national consensus standard it supersedes (see *International Union, UAW* v. *OSHA (LOTO II)*, 37 F.3d 665 (D.C. Cir. 1994); and 58 FR 16612–16616 (March 30, 1993)). Rules promulgated by the Agency must be highly protective (see 58 FR 16612, 16614–15 (March 30, 1993); *LOTO II*, 37 F.3d 665, 669 (D.C. Cir. 1994)). Moreover, section 8(g)(2) of the Act authorizes OSHA ''to prescribe such rules and regulations as [it] may deem necessary to carry out its responsibilities under the Act'' (see 29 U.S.C. 657(g)(2)). OSHA adopted the respirator standard in accordance with these requirements (63 FR 1152).

Appendix A, part II of the respirator standard requires OSHA to commence a rulemaking to adopt an alternative fit test protocol where an applicant provides a detailed description the protocol supported by a test report from an independent laboratory or a published study in a peer-reviewed industrial hygiene journal showing that the protocol is accurate and reliable. In such cases, OSHA relies on the authority in section 6(b)(7) of the OSH Act. This provision allows the Agency to make updates to technical monitoring, measuring, and medical examination requirements in a standard to reflect newly developed information using the informal rulemaking notice

and comment procedures of section 553 of the Administrative Procedure Act, rather than the more elaborate procedures of section 6(b) of the Act. In this case, TSI's proposed protocols are supported by three articles in a peer-reviewed industrial hygiene journal. Each article described one of the proposed protocols and explained how test data support the protocol's accuracy and reliability. Section 6(b)(7) also requires consultation with the Secretary of Health and Human Services, and here OSHA has consulted informally with NIOSH about TSI's proposed protocols. OSHA anticipates that NIOSH will submit formal comments in response to this proposal.

Based on all the submitted information, and after consultation with NIOSH, OSHA has preliminarily determined that the modified PortaCount® protocols provide employees with protections comparable to protections afforded them by the standard PortaCount® protocol already approved by the Agency. OSHA has also made a preliminary finding that the proposed rule is technologically feasible because the protective measures it requires already exist.

As OSHA has explained before, Congress adopted section 6(b)(7) to provide a simple, expedited process to update technical requirements in Agency standards to ensure that they reflect current experience and technological developments (see 77 FR 17602). OSHA believes that the provision of an expedited process to provide technical updates to existing standards shows Congress's intent that new findings of significant risk are unnecessary in such circumstances (see id.). But even if OSHA was proceeding under its normal standard setting requirements, it would need to make no new showing of significant risk because the new protocols would not replace existing fit-testing protocols, but instead would be alternatives to them. OSHA believes that the proposal would not directly increase or decrease the protection afforded to employees, nor would it increase employers' compliance burdens. As demonstrated in the following section, the proposal may reduce employers' compliance burdens by decreasing the time required to fit test respirators for employee use.

B. Preliminary Economic Analysis and Regulatory Flexibility Certification

The proposal is not economically significant within the context of 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 proposal would impose no additional costs on any private- or public-sector entity, and does not meet any of the criteria for a significant or major rule specified by Executive Order 12866 or other relevant statutes. This rulemaking allows employers increased 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) as a result of this rule if the fit-testing method(s) currently in use meets existing standards. Furthermore, as discussed, because the proposed rule offers additional options that employers would select only if those options imposed no net cost burden on them, the proposed rule would not have a significant economic impact on a substantial number of small entities.

The Agency is proposing to supplement the quantitative fit-testing (QNFT) protocols currently in appendix A of the Respiratory Protection Standard, including the standard PortaCount® protocol, with the proposed modified protocols. This would provide employers additional options to fit test their employees for respirator use. Employers already using the standard PortaCount® protocol would have a choice between the existing standard PortaCount® protocol, which consists of eight exercises lasting one minute each, or the proposed protocols, which OSHA estimates would save 4.8 minutes per fit test. This time saving would provide a corresponding cost saving to the employer.

According to TSI, the PortaCount® manufacturer, ''[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 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'' (TSI, 2015b). There are approximately 12,000 Model 8030 or 8038 units in the field, significantly more than the discontinued Model 8020. The time required to adopt the new proposed protocols is expected to be minimal for existing PortaCount® users. The users will be able to update the firmware and software, which is estimated to take less than 5 minutes, and the fit tester would be able to select the proposed protocol or the currently existing test in 29 CFR 1910.134. The updates can be installed at the establishment's location; they do not need to be sent into the manufacturer to load. For the individual being fit tested, it is also likely to take minimal time to gain an understanding of the new protocols. The existing respiratory protection rule contains an annual training component, and information about the new protocol could be imparted during that time, thus adding no additional burden to the employer or employee (TSI, 2015c). OSHA anticipates that the proposed protocols would be adopted by many employers who currently use the standard PortaCount® protocol for their employees. These employers would adopt the proposed protocols because they would take less time to administer than the standard PortaCount® protocol, thereby decreasing the labor cost required for fit testing their employees.

Other establishments use either some other form of quantitative fit testing or qualitative fit testing. The Agency expects that the proposed 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 they already will have made to administer these fit tests. For example, it is estimated that switching from qualitative to quantitative fit testing would require an upfront investment of between $8,000 and $12,000 (TSI, 2015c).

While the Agency 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, what is not known is how many respirator wearers, that is, employees, are fit tested using a PortaCount® device. The Agency expects that economies of scale would apply in this situation—larger establishments would be more likely to encounter situations needing QNFT, but would also have more employees over which to spread the capital costs. Once employers have invested capital in a quantitative fit-testing device, they are likely to perform QNFT on a number of other devices and users, even if not all those devices require QNFT. If sufficiently large, some employers apparently choose to invest in a QNFT device, even though none of the respirator users may technically be required to use a QNFT. Also, some QNFT devices are acquired by third parties, or ''fit-testing houses,'' that provide fit-testing services to employers. In short, employers using PortaCount®

QNFT will not be average size establishments for the purpose of estimating the number of respirator wearers. Some of these establishments might use them for hundreds or possibly thousands of respirator wearers in the course of a year. Alternately, one could look at the number of respirator users estimated to be using respirators that would presumably require QNFT, although it is uncertain what percentage of the QNFT market utilizes the PortaCount® technology currently; also uncertain is the percentage of users of optional QNFT devices using QNFT currently.

Nonetheless, it is possible to develop a plausible estimate of the number of potentially affected respirator wearers, in which these two sets of data converge. For example, if one starts with an estimate of 12,000 establishments using PortaCount® models 8030 and 8038 annually for all of their employees and assumes an average of 100 respirator wearers fit tested annually per establishment, this would yield an estimate of 1.2 million respirator wearers that could potentially benefit from the new QNFT protocol.[2] Alternately, a similar estimate can be obtained if one assumes 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.[3] At a loaded wage rate of $33.81 and assuming savings of 5 minutes per respirator wearer per year, this would imply an annual savings for respirator wearers of approximately $3.4 million.[4] There would also likely be some time savings for the person administering the fit tests. The time saved may potentially be as much as a one-to-one ratio between the tester and those being tested. The Agency solicits comment on the practical experience of employers and others administering fit tests as to the likely effects on total labor productivity (or potentially other cost elements) from being able to expedite the fit-testing process. As discussed, this does not include potential conversions from other types of fit-testing methods currently being used. Alternately, it is possible that some of these assumptions could be overestimates or that some employers are simply comfortable with the existing method and would continue to use the existing protocol despite the potential time savings.

[2] TSI estimated the number of users of their devices at over 12,000 establishments (TSI, 2015c). This is consistent with data from the 2001 NIOSH respirator survey (NIOSH, 2003), which, if benchmarked to a 2012 count of establishments (Census Bureau, 2012) 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.

[3] NIOSH respirator survey (NIOSH, 2003), benchmarked to 2012 County Business Patterns (Census Bureau, 2012). These estimates are based only on private employers. Governmental entities would account for an even larger number of respirator users.

[4] Mean wage rate of $23.23 (BLS, 2016a), assuming fringe benefits are 31.3 percent of total compensation (BLS, 2016b).

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 proposed rule to determine whether these proposed requirements would have a significant economic impact on a substantial number of small entities. This proposed rule would impose no required costs and could provide a cost savings in excess of $3 million per year to regulated entities. The Assistant Secretary for Occupational Safety and Health therefore certifies that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The purposes of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* include enhancing the quality and utility of information the Federal government requires and minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information (paperwork), including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) under the PRA and displays a currently valid OMB control number; the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. When a NPRM includes an information collection, the sponsoring agency must submit a request to the OMB in order to obtain PRA approval. OSHA is submitting an Information Collection Request (ICR), concurrent with the publication of this NPRM. A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201511-1218-005* (this link will only become active on the day following publication of this notice) or by contacting Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

The proposed protocols of this NPRM would revise the information collection in a way that reduces existing burden hours and costs. In particular, the paperwork requirement specified in paragraph (m)(2) of OSHA's Respiratory Protection Standard, at 29 CFR 1910.134, specifies that employers must document and maintain the following information on quantitative fit tests administered to employees: The name or identification of the employee tested; the type of fit test performed; the specific make, model, style, and size of respirator tested; the date of the test; and the 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 could be reduced since some of the proposed protocols would take an employer less time to administer that those currently approved in appendix A. OSHA accounts for this burden under the Information Collection Request, or paperwork analysis, for the Respiratory Protection Standard (OMB Control Number 1218–0099).

OSHA has estimated that the addition of a new protocol, which takes less time to administer, will result in a burden hour reduction of 150,432 hours. OSHA has submitted a revised Respiratory Protection ICR reflecting this reduction to OMB. As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), OSHA is providing the following summary information about the Respiratory Protection information collection:

Title: Respiratory Protection Standard (29 CFR 1910.134).

Number of respondents: 616,035.

Frequency of responses: Various.

Number of responses: 23,443,707.

Average time per response: Various.

Estimated total burden hours: 6,971,401.

Estimated costs (capital-operation and maintenance): $296,098,562.

The Agency solicits comments on these determinations. In addition, the Agency is particularly interested in comments that:

- Evaluate whether the collections of information are necessary for the proper

performance of the Agency's functions, including whether the information is useful;

• Evaluate the accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;

• Evaluate the quality, utility and clarity of the information collected; and

• Evaluate ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

Members of the public who wish to comment on the Agency's collection of information may send their written comments to the Office of Information and Regulatory Affairs, Attn: Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, Washington DC 20503. You may also submit comments to OMB by email at *OIRA.submission@omb.gov* (please reference control number 1218–0099 in order to help ensure proper consideration). The Agency encourages commenters also to submit their comments related to the Agency's clarification of the collection of information requirements to the rulemaking docket (Docket Number OSHA–2015–0006) along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**. You also may obtain an electronic copy of the complete ICR by visiting the Web page at *http://www.reginfo.gov/public/do/PRAMain* and scrolling under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone (202) 693–2222; email *owen.todd@dol.gov.*

D. Federalism

OSHA reviewed the proposal 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, the Agency concludes that this proposed rule 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. The Agency finds that the proposed rulemaking does not expand this limitation. Therefore, for States that do not have approved occupational safety and health plans, this proposed rule would not affect the preemption provisions of Section 18 of the Act.

OSHA's proposal for 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. The Agency preliminarily concludes that the fit-testing protocols proposed by this rulemaking would provide employers in every state with procedures that would assist them in protecting their employees from the risks of exposure to atmospheric hazards. In this regard, the proposal offers thousands of employers across the nation an opportunity to use additional protocols to assess respirator fit among their employees. Therefore, the proposal would provide 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.

Should the Agency adopt a proposed standard in a final rulemaking, Section 18(c)(2) of the Act (29 U.S.C. 667(c)(2)) requires State Plan states to adopt the same standard, or to develop and enforce an alternative standard that is at least as effective as the OSHA standard. However, the new fit-testing protocols proposed in this rulemaking would only 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 would not be obligated to adopt the final provisions that may result from this proposed rulemaking. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide additional compliance options to employers in their states.

In summary, this proposal complies with Executive Order 13132. In states without OSHA-approved State Plans, this proposed rule 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. However, as noted in the previous section of this preamble, states with OSHA-approved State Plans would not be obligated to adopt the final provisions that may result from this proposed rulemaking. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide compliance options to employers in their States. In this regard, OSHA preliminarily concludes that the fit-testing protocols proposed by this rulemaking would provide employers in the State-Plan states with procedures that would protect the safety and health of employees who use respirators against hazardous airborne substances in their workplace at least as well as the existing 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 notice of proposed 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 B of this preamble (''Preliminary Economic Analysis and Regulatory Flexibility Certification''), OSHA preliminarily determined that the proposed rule imposes no additional costs on any private-sector or public-sector entity. The substantive content of the proposed rule applies only to employers whose employees use respirators for protection against airborne contaminants, and compliance with the protocols contained in the proposed rule would be strictly optional for these employers. Accordingly, the proposed rule would require no additional expenditures by either public or private employers. Therefore, this proposal 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 notice of proposed 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 proposal 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.'' In this regard, when OSHA promulgated its original respirator fit-testing protocols under appendix A of its final Respiratory Protection Standard (29 CFR 1910.134), no national consensus standards addressed these protocols. Later, 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).

Paragraph 7.2 of ANSI/AIHA Z88.10–2010 specifies the requirements for conducting a particle-counting instrument (*e.g.,* PortaCount®) quantitative fit test, which differ substantially from the standard PortaCount® protocol provided in appendix A of OSHA's Respiratory Protection Standard. These protocols differ in terms of both the fit-testing exercises required and the duration of these exercises. The proposed modified PortaCount® protocols are variations of the ANSI/AIHA particle-counting instrument quantitative fit test protocol, in that they require the same 30 second duration for fit-testing exercises, but they do not require the same exercises required by 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 a specific procedure and criteria for evaluating new fit-testing methods. The Agency is requiring that in order to be adopted by the Agency, TSI statistically show that its proposed modified PortaCount® protocols meet the ANSI/AIHA Annex A2 performance requirements. The Agency believes that if the proposed modified PortaCount® protocols meet the criteria outlined in ANSI/AIHA Z88.10–2010, Annex A2, then they would be as accurate and reliable as the ANSI/AIHA protocol, but shorter in duration and less costly to administer.

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

The proposal to add two quantitative fit-test protocols to appendix A of OSHA's Respiratory Protection Standard would affect the construction industry because it revises the fit-testing procedures specified by the standard, which is applicable to the construction industry (see 29 CFR 1926.103). Whenever the Agency proposes a rule involving construction activities, 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. 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.'' Accordingly, OSHA provided the ACCSH members with copies of Mr. Niccum's application letter and its supporting documents, along with other relevant information, prior to the December 4, 2014 ACCSH meeting. OSHA staff presented a slide presentation to the ACCSH at that meeting to explain the proposal. At the end of this session, the ACCSH unanimously recommended to proceed with the initiation of a notice-and comment rulemaking under Section 6(b)(7) of the OSH Act to seek public comment on adding proposed new fit-test protocols into appendix A of the Respiratory Protection Standard.

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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

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 directed the preparation of this notice. Accordingly, the Agency issues this notice under the following authorities: 29 U.S.C. 663, 655 and 656, 40 U.S.C. 3701, *et seq.,* Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR part 1911.

Signed at Washington, DC, on September 26, 2016.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendment to the Standard

For the reasons stated in the preamble, the Agency proposes to amend 29 CFR part 1910 as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart I—Personal Protective Equipment

■ 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 appendix A to § 1910.134 as follows:

■ a. Revise the introductory text of paragraph 14(a) in Part I.A.

■ b. In Part I.C.3, revise the introductory paragraph and remove the terms ''Portacount™'' and ''Portacount'' and add in their place the term ''PortaCount®'' wherever they occur.

■ c. In Part I.C, redesignate protocol 4, ''Controlled negative pressure (CNP) quantitative fit testing protocol.'' as protocol 6.

■ d. In Part I.C, redesignate protocol 5, ''Controlled negative pressure (CNP) REDON quantitative fit testing protocol.'' as protocol 7.

■ e. Add new protocols 4 and 5.

■ f. Revise paragraphs (a) and (b) in newly redesignated Part I.C.7.

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. * * *

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the two modified CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified 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) of this appendix 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 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. Two PortaCount® Respirator Fit Tester models are available. One model is used to fit test elastomeric respirators (*i.e.,* full facepiece and half-mask) and filtering facepiece respirators using ≥99% efficient filter media, and another model, with the N95-Companion™ Technology capability, is used to fit test elastomeric respirators (*i.e.,* full facepiece and half-mask) and filtering facepiece respirators with any type of filter media, including those equipped with <99% efficient filter media. 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 below in Table A–1 of this appendix.

TABLE A–1—MODIFIED 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 below in Table A–2 of this appendix.

TABLE A–2—MODIFIED 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 below in Table A–3 of this appendix.

TABLE A–3—CNP REDON QUANTITATIVE FIT TESTING PROTOCOL

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

[1] Exercises are listed in the order in which they are to be administered.

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