DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2007–0006]

RIN 1218–AC29

Abbreviated Bitrex® Qualitative Fit-Testing Protocol

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: OSHA is proposing to include the protocol for the abbreviated Bitrex® qualitative fit test (''ABQLFT'') in its Respiratory Protection Standard; the proposed protocol would apply to employers in general industry, shipyard employment, and the construction industry. The proposed ABQLFT protocol consists of seven exercises described in the existing Bitrex® qualitative fit-testing protocol specified in OSHA's Respiratory Protection Standard. However, each of the exercises in the proposed ABQLFT protocol lasts 15 seconds, compared to 60 seconds for exercises in the existing Bitrex® qualitative fit-testing protocol. This proposal describes the test sensitivity, predictive value of a pass, test specificity, and predictive value of a fail for the ABQLFT protocol, and requests the public to comment on whether this evidence supports OSHA including the ABQLFT in the Respiratory Protection Standard.

DATES: Comments to this proposal, including comments to the information-collection (paperwork) determination described under the **SUPPLEMENTARY INFORMATION** section, must be submitted (postmarked, sent, or received) by February 25, 2008.

ADDRESSES: Comments may be submitted as follows:

- *Electronic:* Comments may be submitted electronically to *http://www.regulations.gov*, which is the Federal eRulemaking portal. Follow the instructions online for submitting comments.
- *Facsimile:* OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Send these comments to the OSHA Docket Office at (202) 693–1648; hard copies of these comments are not required. Instead of transmitting facsimile copies of attachments that supplement their comments (e.g., studies, journal articles), commenters may submit these attachments, in triplicate hard copy, to the OSHA Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. These attachments must clearly identify the sender's name, date, subject, and docket number (i.e., OSHA–2007–0006) so that the Agency can attach them to the appropriate comments.
- *Regular mail, express delivery, hand (courier) delivery, and messenger service:* Submit three copies of comments and any additional material (e.g., studies, journal articles) to the OSHA Docket Office, Docket No. OSHA–2007–0006 or RIN No. 1218–AC29, Technical Data Center, Room N–2625, OSHA, Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; *telephone:* (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Please contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m. to 4:45 p.m., e.t.
- *Instructions:* All submissions must include the Agency name and the OSHA docket number (i.e., OSHA–2007–0006). Comments and other material, including any personal information, are placed in the public docket without revision, and will be available online at *http://www.regulations.gov*. Therefore, the Agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as social security numbers, birth dates, and medical data.
- *Docket:* To read or download comments or other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the address above. Documents in the docket 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 this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Mr. Kevin Ropp, Director, Office of Communications, OSHA, U.S. Department of Labor, Room N–3637, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999; facsimile: (202) 693–1634. For technical inquiries, contact Mr. John E. Steelnack, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; *telephone:* (202) 693–2289; *facsimile:* (202) 693–1678.

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

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I. Background

Appendix A of OSHA's Respiratory Protection Standard at 29 CFR 1910.134 currently includes four qualitative fit-testing protocols using the following challenge agents: isoamyl acetate; saccharin-solution aerosol; Bitrex® (denatonium benzoate) aerosol in solution; and irritant smoke (stannic chloride). Appendix A of the Respiratory Protection Standard also specifies the procedure for adding new test protocols to this standard. The criteria for determining whether OSHA must publish a fit-testing protocol for notice-and-comment rulemaking under Section 6(b)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655) 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.

II. Summary and Explanation of the Proposal

A. Introduction

In the letter submitting the abbreviated Bitrex® qualitative fit-testing (''ABQLFT'') protocol for review under the provisions of Appendix A of OSHA's Respiratory Protection Standard (Ex. OSHA–2007–0006–0002), Dr. Michael L. Runge of the 3M Company included a copy of a peer-reviewed article from an industrial-hygiene journal describing the accuracy and reliability of the proposed ABQLFT protocol (Ex. OSHA–2007–0006–0003). This article also described in detail the equipment and procedures required to administer the proposed ABQLFT protocol. According to this description, the proposed protocol is a variation of the existing Bitrex® qualitative fit-testing protocol developed by the 3M Company in the early 1990s, which OSHA approved for inclusion in the final Respiratory Protection Standard. The proposed ABQLFT protocol uses the same fit-testing requirements and instrumentation specified for the existing Bitrex® qualitative fit-testing protocol in paragraphs (a) and (b) of Part I.B.4 of Appendix A of the Respiratory Protection Standard, with the following two exceptions:

- Exercise times are reduced from 60 seconds to 15 seconds; and
- The proposed ABQLFT protocol is used only with test subjects who can taste the Bitrex® screening solution within the first 10 squeezes of the nebulizer bulb (referred to as ''Level 1 sensitivity'').

B. Summary of the Peer-Reviewed Article

The peer-reviewed article, entitled ''Development of an Abbreviated Qualitative Fit Test Using Bitter Aerosol,'' appeared in the Fall/Winter 2003 issue of the Journal of the International Society for Respiratory Protection (Ex. OSHA–2007–0006–0003). The authors of this study were T.J. Nelson of NIHS, Inc., and L.L. Janssen, M.D. Luinenburg, and H.E. Mullins of the 3M Company; the 3M Company supported the study. This article describes a study that determined whether performing a fit test involving seven exercises lasting 15 seconds each while exposed to Bitrex® (referred to as the abbreviated Bitrex® qualitative fit test or ''ABQLFT'') yielded fit-testing results similar to results obtained with a generated-aerosol (i.e., corn oil) quantitative fit test (''GAQNFT'') using one-minute exercises (i.e., the GAQNFT was the criterion measure or ''gold standard'').

The study involved 43 experienced respirator users, 20 females and 23 males. The test subjects followed the existing Bitrex® qualitative fit-testing protocol in Appendix A of OSHA's Respiratory Protection Standard except that they performed each of the fit-testing exercises for 15 seconds (instead of 60 seconds) while wearing a NIOSH-certified elastomeric half-mask respirator equipped with P100 filters. The authors selected the best fitting respirator for each test subject from among four models, each available in three sizes; some test subjects used more than one model during fit testing. In addition, the authors induced poor respirator fits by assigning a respirator to test subjects that was one or two sizes too small or too large as determined by the Los Alamos National Laboratory panel-grid size and observation of the test subjects' facial characteristics. Test subjects could adjust the respirator facepiece for comfort, but they did not perform user seal checks.

In conducting the study, the authors used the recommendations for evaluating new fit-test methods specified by Annex A2 of ANSI Z88.10–2001, including sequencing the ABQLFT and GAQNFT in random order without disturbing facepiece fit. The authors used fit-test sample adaptors or respirators with fixed probes to collect samples inside the respirator. The sample point inside the respirator was located between the nose and the mouth. For both fit tests, the authors had the test subjects perform seven of the eight exercises listed in Part I.A.14 of Appendix A of OSHA's Respiratory Protection Standard, which included: normal breathing, deep breathing, turning the head side to side, moving the head up and down, reading a passage, bending over, and normal breathing.[1] For the GAQNFT, the authors performed particle counts at one-second intervals inside a test chamber for 15–30 seconds before and after fit testing, and inside the respirator for the 60-second duration of each exercise.

The 43 test subjects used in the study had Level 1 sensitivity to Bitrex® because they were able to taste the Bitrex® aerosol within 10 squeezes of the nebulizer bulb. Subjects having Level 2 or 3 sensitivity to Bitrex® were excluded from further participation in thestudy because the nebulizer could not be replenished for additional taste testing within the 15 seconds allotted to perform each fit-testing exercise. After the test subjects passed a Bitrex® sensitivity-screening test, the authors administered the ABQLFT using the procedures and techniques specified for the existing Bitrex® qualitative fit-testing protocol in Part I.B.14 of Appendix A of OSHA's Respiratory Protection Standard, and determined the fit factor using the particle count for the 15-second duration of each exercise.

The authors required a fit factor of 100 to pass a fit test, which served as the basis for determining the following statistics for the ABQLFT: test sensitivity; predictive value of a pass; test specificity; and predictive value of a fail. In calculating these statistics, the authors adopted the variables defined by ANSI Z88.10–2001, in which: A = false positives (passed the fit test with a fit factor < 100); B = true positives (passed the fit test with a fit factor > 100); C = true negatives (failed the fit test with a fit factor ≥ 100); and D = false negatives (failed the fit test with a fit factor ≥ 100). Using these variables, ANSI Z88.10–2001 specifies the formula and recommended value (''RV'') for each statistic as follows: Test sensitivity = C / (A + C), RV > 0.95; predictive value of a pass = B / (A + B), RV > 0.95; test specificity = B / (B + D), RV > 0.50; and predictive value of a fail = C / (C + D), RV > 0.50.

Using the GAQNFT as the criterion measure, the variables for the ABQLFT had the following values: A = 4; B = 95; C = 48; and D = 20. The statistics calculated for the ABQLFT from these values were: test sensitivity = 0.92; predictive value of a pass = 0.96; test specificity = 0.83; and predictive value of a fail = 0.71. Therefore, every statistic for the ABQLFT, except test sensitivity, attained a value in excess of the ANSI Z88.10–2001 recommended value.

The test-sensitivity value of 0.92 for the ABQLFT fell below the ANSI recommended value of 0.95. The authors state that this slight difference represents a single false positive value for the ABQLFT (i.e., failed the GAQNFT but passed the ABQLFT). However, an additional peer-reviewed article submitted by Dr. Runge of the 3M Company suggests an alternative approach to examining these test-sensitivity values (see Ex. OSHA–2007–0006–0004). This article, entitled ''Recommendations for the Acceptance Criteria for New Fit Test Methods'' and published in the Spring/Summer 2004 issue of the *Journal of the International Society for Respiratory Protection*, describes an analytical study conducted

[1] The test subjects did not perform the grimace exercise.

by T.J. Nelson of NIHS, Inc. and H. Mullins of the 3M Company, and supported by the 3M Company. In this study, the authors performed a binary logistic-regression analysis on pass-fail fit-testing data from published studies involving two quantitative, and two qualitative, fit tests. The authors justify using the binary logistic-regression analysis for this purpose as follows:

> When a simple sensitivity test is used to describe a new test, the result can be affected by the distribution of the data. In several cases using the theoretical distributions described in this paper, the outcome of a sensitivity test for the Bitrex and Ambient Particle Counter fit tests could have failed to meet the ANSI Z88.10 sensitivity requirement. The method used to determine acceptability should be independent of specific data collected. (See Ex. OSHA–2007–0006–0004, p. 8.)

The results of the binary logistic-regression analysis performed on the ABQLFT data showed that the ABQLFT had a 0.20 probability of passing a respirator user with a fit factor of 50 and a 0.33 probability of passing a respirator user with a fit factor of 100. Figure 3 of the article compares the binary logistic-regression analysis results of test-sensitivity values obtained for a popular quantitative fit test and the existing 60-second Bitrex® qualitative fit test. The authors conclude that the analysis demonstrates that the distribution of fit-testing data affected the test-sensitivity values derived using the ANSI Z88.10–2001 test-sensitivity calculations. Based on this analysis, the authors assert that ''a sensitivity calculation may not be the best indicator of fit test method performance. The binary logistic regression analysis shows that the result of the 15 second exercise time test is very similar to the ambient aerosol and 60 second bitter aerosol tests'' (Ex. OSHA–2007–0006–0003, p. 108). In summarizing the study's results, the authors state that ''[t]he 15 second bitter aerosol protocol sufficiently screens for adequate respirator fit in subjects with Level 1 Bitrex taste sensitivity.''

C. Conclusions

OSHA believes that the information submitted by Dr. Runge in support of the proposed ABQLFT protocol meets the criteria for proposed fit-testing protocols established by the Agency in Part II of Appendix A of its Respiratory Protection Standard. Therefore, the Agency concludes that the proposed ABQLFT protocol warrants notice-and-comment rulemaking under Section 6(b)(7) of the OSH Act, and is initiating this rulemaking to determine whether to approve the proposed protocol for inclusion in Part I of Appendix A of its Respiratory Protection Standard.

An important difference between the proposed ABQLFT protocol and the existing Bitrex® qualitative fit-testing protocol specified currently in Part I.B.4 of Appendix A of the Respiratory Protection Standard is the duration of the exercises used during fit testing. The Agency is taking comments on whether to add the ABQLFT protocol to Part I.B.4 of Appendix A (see section IV, ''Proposed Amendment to the Standard,'' below); in addition to decreasing exercise durations from 60 seconds to 15 seconds each, the new regulatory text would limit use of the proposed ABQLFT to respirator users who demonstrate Level 1 sensitivity to Bitrex®. If approved, the proposed ABQLFT protocol would be an alternative to the existing qualitative fit-testing protocols already listed in the Part I of Appendix A of the Respiratory Protection Standard; employers would be free to select this alternative or to continue using any of the other protocols currently listed in the Appendix.

D. Issues for Public Comment

OSHA invites comments and data from the public regarding the accuracy and reliability of the proposed ABQLFT protocol, its effectiveness in detecting respirator leakage, and its 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 studies described in the submitted articles well controlled, and conducted according to accepted experimental design practices and principles?
- Were the results of the studies described in the submitted articles properly, fully, and fairly presented and interpreted?
- Will the proposed ABQLFT protocol generate reproducible fit-testing results, and what additional experiments or analyses of existing data are necessary to answer this question?
- Will the proposed ABQLFT protocol reliably identify respirators with unacceptable fit as effectively as the qualitative fit-testing protocols, including the existing Bitrex® qualitative fit-testing protocol, already listed in Part I.B of Appendix A of the Respiratory Protection Standard?
- What is the significance of the test-sensitivity value of 0.92 obtained for the ABQLFT relative to the test-sensitivity value of 0.95 recommended by ANSI Z88.10–2001, and does the authors' assertion that ''a sensitivity calculation may not be the best indicator of fit test method performance'' adequately account for the lower test-sensitivity value?
- What is the significance of limiting the ABQLT to respirator users who demonstrate Level 1 sensitivity to Bitrex®?

III. Procedural Determinations

A. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (''OSH 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) and 654(b).) 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 OSH Act when a significant risk of material harm exists in the workplace, and the standard will substantially reduce or eliminate that workplace risk.

Employers covered by this proposal already must comply with the fit-testing requirements specified in paragraph (f) of OSHA's Respiratory Protection Standard at 29 CFR 1910.134. Accordingly, these provisions currently are protecting their employees from the significant risk that results from poorly fitting respirators. For this proposal, the Agency preliminarily determined that the proposed ABQLFT fit-testing protocol provides employees with protection that is comparable to the protection afforded to them by the existing Bitrex® qualitative fit-testing provisions. In this regard, the proposal is not expected to replace existing fit-testing protocols, but instead would be an alternative to them. Therefore, OSHA preliminarily finds 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. Accordingly, OSHA concludes that it is unnecessary to determine significant risk or the extent to which this proposal

would reduce that risk, as typically would be required by *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

B. Preliminary Economic Analysis and Regulatory Flexibility Certification

The proposal is not economically significant within the context of Executive Order (''E.O.'') 12866 (58 FR 51735). Additionally, the proposal is not a ''major rule'' under Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''; 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 an economically significant or major rule specified by E.O. 12866 or other relevant statutes.

The proposal offers employers an additional option to fit test their employees for respirator use. In addition to the existing Bitrex® qualitative fit-testing protocol, which would continue to be an option, the Agency would add the ABQLFT protocol as a supplemental option if OSHA approves it as a result of this proposed rulemaking. According to a recent National Institute for Occupational Safety and Health-Bureau of Labor Statistics survey of respirator use, approximately 25,000 establishments currently use the existing Bitrex® qualitative fit-testing protocol out of nearly 282,000 establishments requiring respirator use (Ex. 6–3, Docket H–049C).

Under this proposal, employers would have a choice between any of the existing fit-testing protocols, including the existing Bitrex® qualitative fit-testing protocol consisting of exercises lasting one minute each, or the new ABQLFT protocol. By providing regulatory flexibility to these employers, the proposal may reduce their costs by decreasing fit-testing time. In this regard, OSHA assumes that the proposed ABQLFT protocol would be adopted by some employers who use the existing Bitrex® qualitative fit-testing protocol for those employees with Level 1 sensitivity. These employers would adopt the proposed ABQLFT protocol because it consists of exercises lasting a shorter duration than the exercises in the existing Bitrex® qualitative fit-testing protocol, thereby decreasing the time and cost required for fit testing their employees. However, the Agency believes that the proposed protocol is unlikely to be adopted by employers who currently use the generated-aerosol, ambient-aerosol condensation-nuclei counter, or contingent-negative pressure quantitative fit-testing systems because of the significant equipment and training investment they already have made to administer these fit tests.

Based on the above discussion, the Agency preliminarily concludes that this proposed rulemaking would impose no additional costs on employers, thereby eliminating the need for a preliminary economic analysis. Moreover, OSHA certifies that the proposal would not have a significant impact on a substantial number of small entities, and that the Agency does not have to prepare an initial regulatory flexibility analysis for this rulemaking under the SBREFA (5 U.S.C. 601 *et seq.*).

C. Paperwork Reduction Act

After thoroughly analyzing the proposed fit-testing provisions in terms of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.* and 5 CFR part 1320), OSHA believes that these provisions would not add to the existing collection-of-information (i.e., paperwork) requirements regarding fit testing employees for respirator use. The paperwork requirement specified in paragraph (m)(2) of OSHA's Respiratory Protection Standard at 29 CFR 1910.134 specifies that employers must document and maintain the following information on qualitative 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. However, this paperwork requirement would remain the same whether employers currently use the other fit-testing protocols already listed in Part I of Appendix A of the Respiratory Protection Standard, or implement the proposed fit-testing protocol instead. Therefore, using the proposed fit-testing protocol in the context of the existing fit-testing protocols would not involve an additional paperwork-burden determination by OSHA because it already accounts for this burden under the paperwork analysis for the Respiratory Protection Standard (OMB Control Number 1218–0099).

Members of the public may send comments on this paperwork analysis to: Office of Information and Regulatory Affairs (Attention: Desk Officer for OSHA), Office of Management and Budget, Room 10235, 725 17th Street, NW., Washington, DC 20503. The Agency also encourages commenters to submit a copy of their comments on this paperwork analysis to OSHA, along with their other comments on the proposed rule.

D. Federalism

The Agency reviewed the proposal according to the most recent Executive Order (''E.O.'') on Federalism (E.O. 13132; 64 FR 43225), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that restrict their policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. E.O. 13132 allows Federal agencies to preempt State law only with the expressed consent of Congress. In such cases, Federal agencies must limit preemption of State law to the extent possible.

Under Section 18 of the Occupational Safety and Health Act of 1970 (''OSH Act''; 29 U.S.C. 651 *et seq.*), Congress expressly authorizes OSHA to preempt State occupational safety and health standards. Under the OSH Act, a State can avoid such preemption only when it has an OSHA-approved occupational safety and health plan (*i.e.*, is a ''State-plan State''; see 29 U.S.C. 667). Occupational safety and health standards developed by a State-Plan State must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to the limitations specified by the OSH Act at 29 U.S.C. 667, State-Plan States are free to develop and enforce their own requirements for safety and health standards under State law.

This proposed rulemaking complies with E.O. 13132. In States without OSHA-approved State Plans, Congress expressly provides for Agency standards to preempt State job safety and health rules in areas addressed by the Federal standards; in these States, the proposed rule would limit State policy options in the same manner as every OSHA standard. Therefore, with respect to States that do not have OSHA-approved plans, the Agency concludes that this proposal conforms to the preemption provisions of the OSH Act. Additionally, Section 18 of the OSH Act prohibits States without approved plans from issuing citations for violations of OSHA standards; the Agency finds that the proposed rulemaking does not expand this limitation.

OSHA has authority under E.O. 13132 to propose the use of the ABQLFT protocol under its Respiratory Protection Standard at 29 CFR 1910.134 because the problems addressed by these fit-testing requirements are national in scope. In this regard, the proposal offers hundreds of thousands of employers across the nation an

opportunity to use an additional protocol 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 in 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 OSH Act (29 U.S.C. 667(c)(2)) requires State-plan States to adopt the same standard, or develop an alternative that is at least as effective as the OSHA standard. However, the new fit-testing protocol proposed in this rulemaking would only provide employers with an alternative to the existing requirements for 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 rulemaking. Nevertheless, OSHA strongly encourages them to adopt the final provisions to provide compliance options to employers in their States.

E. State-Plan States

When Federal OSHA promulgates a new standard or imposes additional or more stringent requirements than an existing standard, the 26 States and U.S. Territories with their own OSHA-approved occupational safety and health plans (*i.e.*, ''State-Plan States'') must revise their standards to reflect the new OSHA standard or amendment, or show the Agency why such action is unnecessary (*e.g.*, because an existing State standard covering this area already is at least as effective in protecting employees as the new Federal standard or amendment (29 CFR 1953.5(a)). The State standard must be (1) at least as effective as the final Federal rule in protecting employees, (2) applicable to both the private and public (*i.e.*, State and local government employees) sectors, and (3) completed within six months of the publication date of the final Federal rule.

When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State-Plan States are not required to revise their standards, although the Agency may encourage them to do so. Accordingly, the Agency strongly encourages the 26 States and U.S. Territories with their own OSHA-approved occupational safety and health plans to revise their current Respiratory Protection Standard should the Agency adopt the proposed fit-testing protocol based on this rulemaking. OSHA preliminarily concludes that such a revision would provide employers in the State-plan States with any economic benefits that may accrue from such enactment, while protecting the safety and health of employees who use respirators against hazardous airborne substances in the workplace at least as well as the existing Bitrex® qualitative fit-test protocol. These States and U.S. Territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to State and local government employees only.

F. Unfunded Mandates Reform Act

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

As noted above under section III.E (''State-Plan States'') of this preamble, OSHA standards do not apply to State and local governments except in States that have voluntarily elected to adopt a State Plan approved by the Agency. Consequently, this proposal does not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5))). Therefore, for the purposes of the UMRA, the Agency certifies that the 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

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. However, the American National Standards Institute (ANSI) subsequently 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.

Paragraph 7.3 of ANSI Z88.10–2001 provides the requirements for conducting the Bitrex® qualitative fit test, including requirements for administering the fit test; these requirements are consistent with the existing Bitrex® qualitative fit-testing requirements specified in Part I.B.4 of OSHA's Respiratory Protection Standard, except that the ANSI exercises must last at least 30 seconds each while the exercises required by the OSHA standard must last 60 seconds each. In addition, section 9 and Table 1 of ANSI Z88.10–2001 describe the exercises required during fit testing; these exercises duplicate the exercises described in the proposed ABQLFT protocol, except that, as noted previously, the ANSI standard requires that the test exercises last at least 30 seconds each.

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

By adding the ABQLFT as an optional qualitative fit-testing protocol to Part I.B of Appendix A of OSHA's Respiratory Protection Standard,[2] this proposal would revise the fit-testing requirements specified by that standard for the construction industry. Whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees, OSHA's regulation governing the ACCSH at 29 CFR 1912.3 requires the Agency to consult with the ACCSH. Having provided the ACCSH members with copies of the proposal and other relevant information several weeks before the regular meeting, OSHA staff then met with them at the regular meeting on October 11, 2006. At this meeting, OSHA staff discussed the proposal with, and answered questions from, the ACCSH members. At their regular meeting the following day (October 12, 2006), the ACCSH members recommended, by a vote of nine in favor with one abstention, that OSHA publish the proposal.

[2] The Respiratory Protection Standard for the construction industry at 29 CFR 1926.103 cross-references Respiratory Protection Standard for general industry at 29 CFR 1910.134.

List of Subjects in 29 CFR Part 1910

Hazardous substances, Health, Occupational safety and health, Toxic substances.

Authority and Signature

Edwin G. Foulke, Jr., 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 the proposed amendment under the following authorities: Sections 4, 6(b), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 5–2007 (72 FR 31159); and 29 CFR part 1911.

Signed at Washington, DC on December 17, 2007.

Edwin G. Foulke, Jr.,

Assistant Secretary of Labor for Occupational Safety and Health.

IV. Proposed Amendment to the Standard

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

PART 1910—[AMENDED]

Subpart I—[AMENDED]

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

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Section 41, Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); and Secretary of Labor's Order Nos. 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), as applicable.

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

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

2. Amend section B.4(b)(8) of Appendix A to § 1910.134 to read as follows:

§ 1910.134 Respiratory protection.

* * * * *

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

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B. * * *

4. * * *

(b) * * *

(8) After generating the aerosol, the employer shall:

(i) Instruct the test subject to perform the exercises specified by section I.A.14 of this appendix; and

(ii) Ensure that the test subject performs each of these test exercises for one minute; however, if the test subject is able to detect the taste of the Bitrex® sensitivity screening solution within the first 10 squeezes of the nebulizer bulb (''Level 1 sensitivity''), the employer may elect to have the test subject perform each of the test exercises for a minimum of 15 seconds.

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DEPARTMENT OF EDUCATION

34 CFR Part 8

[Docket ID ED–2007–OS–0138]

Demands for Testimony or Records in Legal Proceedings

AGENCY: Office of the Secretary, Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the Department's regulations regarding the production of information pursuant to demands in judicial or administrative proceedings. The changes are intended to promote consistency in the Department's assertion of privileges and objections, and thereby prevent harm that may result from inappropriate disclosure of confidential information or inappropriate allocation of agency resources. These changes would apply only where employees are subpoenaed in litigation to which the agency is not a party. Former Department employees would be expressly required to seek the Secretary's approval prior to responding to subpoenas that seek non-public materials and information acquired during their employment at the Department.

DATES: We must receive your comments on or before February 25, 2008.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by e-mail. Please submit your comments only one time, in order to ensure that we do not receive duplicate copies. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* Under ''Search Documents'' go to ''Optional Step 2'' and select ''Department of Education'' from the agency drop-down menu; then click ''Submit.'' In the Docket ID column, select ED–2007–OS–0138 to add or view public comments and to view supporting and related materials available electronically. Information on using *www.regulations.gov,* including instructions for submitting comments, accessing documents, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail, Commercial Delivery, or Hand Delivery.* If you mail or deliver your comments about these proposed regulations, address them to Christine M. Rose, U.S. Department of Education, 400 Maryland Avenue, SW., Room 6C122, Washington, DC 20202–2110.

Privacy Note: The Department's policy for comments received from members of the public (including those comments submitted by mail, commercial delivery, or hand delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at *http://www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the Internet.

FOR FURTHER INFORMATION CONTACT: Christine M. Rose, *Telephone:* (202) 401–6700.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:

Invitation to Comment

We invite you to submit comments regarding these proposed regulations. To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses and to arrange your comments in the same order as the proposed regulations.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further opportunities we should take to reduce potential costs or