National Institute for Occupational Safety and Health

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Comments to OSHA

Comments of the National Institute for Occupational Safety and Health on the Occupational Safety and Health Administration's Notice of Proposed Rulemaking and Request for Comments on Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard

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Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
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The National Institute for Occupational Safety and Health (NIOSH) has reviewed the Occupational Safety and Health Administration (OSHA) notice of proposed rulemaking (NPRM) and request for comments on *Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard* published in the *Federal Register* [81 FR 69740] on October 7, 2016. NIOSH has reviewed the evaluation articles of the three fast PortaCount® fit test protocols and determined that they conform to the requirements of Annex 2,"Criteria for Evaluating New Fit Test Methods" of the American National Standards Institute (ANSI)/ American Industrial Hygiene Association (AIHA) Z88.10-2010 standard. NIOSH recommends that OSHA accept the three protocols. NIOSH offers the following responses to the OSHA questions on page 69745 (questions in bold).

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

  Comment: NIOSH reviewed the three studies and concluded they were conducted in accordance with Annex 2, "Criteria for Evaluating New Fit Test Methods" of the ANSI/AIHA Z88.10-2010 standard using sound (or acceptable) laboratory practices. The NPRM does note on page 69742 (Fast-Half Method), that the NIOSH bivariate panel was used for conducting the referenced study and that *"...no subjects were in cells 6, 9 or 10 (those with longer—nose to chin—face sizes)."* For the Fast-Full Method (page 69743), no subjects were in cells 1 (very small) or 10 (very large). For the Fast-FFR Method for filtering face-piece respirators (FFR) (page 69744), there were no subjects in cells 9 or 10 (*those with longer—nose to chin—face sizes).* Annex 2, "Criteria for Evaluating New Fit Test Methods" of the ANSI/AIHA AZ88.10-2010 standard does not specify the face sizes of the subjects. For future reference and clarity, NIOSH recommends providing a rationale for not using individuals in those cells cited since the studies included using the NIOSH bivariate panel to have subjects with varying facial sizes and shapes. Also, NIOSH understands the subjects with facial dimensions within certain cells were not available for testing and were not excluded to influence the results.

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

  Comment: NIOSH reviewed the methodology and results for conformance with the requirements described in ANSI/AIHA Z88.10-2010. Since the studies conformed to the ANSI Z88.10 requirements, NIOSH determined the results of the three studies cited in the *Federal Register* notice were properly described and interpreted by the authors.

- **Did the three studies treat outliers appropriately in determination of the exclusion zone?**

  Comment: In the manuscripts, outliers were identified as data more than three standard deviations from the mean of the remaining data points. This is a reasonable method for diagnosing/identifying outliers [Grubbs 1969]. "Normal breathing" is an appropriate exercise to use for TSI Incorporated's (TSI) baseline fit because it is performed while the subject is breathing without exertion or moving their head or talking. Thus, one would expect that if the respirator fit did not change between the two fit test methods (i.e., the "reference" method and the Fast-Fit method), that the fit factors for "normal breathing" would be similar. If the fit changes by more than a factor of 100 (e.g., from 200 to 2), it would be reasonable to conclude that the baseline fit had changed. Although the basis for choosing a ratio of 100 for their study is not explained in TSI Journal of the International Society for Respiratory Protection (JISRP) publications and appears to be arbitrary, without other objective information on which to base a decision, a ratio of 100 appears to be reasonable.

- **Will the two proposed protocols generate reproducible fit-testing results?**

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

- **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?**

  Comment: TSI used the ANSI Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" to demonstrate that their new PortaCount® Fast-Fit methods could identify poorly fitting respirators as effectively as the OSHA-accepted PortaCount® method. The results of the studies cited in the NPRM (i.e., Richardson et al. 2013, Richardson et al. 2014a, Richardson et al. 2014b) provide evidence that using this criteria, their new PortaCount® Fast-Fit methods can identify poorly fitting respirators as effectively as the OSHA-accepted PortaCount® method. Evidence is not available in the literature to assess whether the two proposed protocols reliably identify respirators with unacceptable fit as effectively as the other accepted quantitative fit-testing protocols (generated aerosol and controlled negative pressure (CNP)). It is recommended that further side-by-side studies be conducted to test the equivalency of the new PortaCount®

Fast-Fit methods in identifying poorly fitting respirators as effectively as the OSHA-accepted CNP testing; potentially, tests using other "generated aerosols" would be needed to determine whether the methods are equivalent.

- **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?**

  Comment: NIOSH reviewed the data (i.e., the three studies) from the proposed fast methods to determine if they met the criteria contained in the ANSI/AIHA Z88.10-2010, Annex A2, Criteria for Evaluating Fit Test Methods. This review examined whether the sensitivity, predictive value of a pass, test specificity, predictive value of a fail and the kappa statistic presented in the tables were consistent with the fit factor data presented in the figures (e.g., Table VII Comparison of Measured ANSI Analysis Statistics with ANSI Criteria for Fast-Full Method to be Acceptable and Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-Full Fit Test Methods in the manuscript, "Evaluation of a faster fit testing method for full-facepiece respirators based on the TSI PortaCount®"). The review determined that the three methods met the criteria contained in the ANSI/AIHA Z88.10-2010, Annex A2.

- **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?**

  Comment on all questions: NIOSH recommends providing references to support that the jogging-in-place exercise used in the Fast-Full and Fast-Half protocols is aggressive in evaluating the respirator seal.

  Since the jogging-in-place exercise is used in the Fast-Half protocol to evaluate the seal, it should be used in the Fast-FFR protocol as well, unless there are valid reasons for not doing so.

  No reasoning was provided with the Fast-FFR protocol for not replacing the talking with the jogging-in-place exercise.

- **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?**

Comment on all questions: The grimace exercise intentionally breaks the seal to assess whether the mask reseals to the user's face if broken for a brief time. The protocols provide a valid reason for not including it in the method comparison testing since it would add a non-controlled variable. However, NIOSH recommends that the grimace test be included in the abbreviated protocols when used in the workplace since it is part of the currently accepted protocols. The lack of this exercise/facial movement leaves questions as to whether the same level of protection is provided by the abbreviated protocols when testing workers in the workplace. Further research on this issue is needed to determine if the grimace can be omitted from the proposed protocols as well as the currently accepted protocols.

- **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?**

  Comment on both questions: NIOSH is unaware of any previous studies that support the assertion that including taking 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 in the protocol make the test more rigorous. NIOSH does not have any concerns about including these deep breaths.

References

Coffey CC, Lawrence RB, Zhuang Z, Campbell DL, Jensen PA, Myers WR [2002]. Comparison of five methods for fit-testing N95 filtering-facepiece models. Appl Occup Environ Hyg *17*:723–730, http://www.tandfonline.com/doi/pdf/10.1080/10473220290107002?needAccess=true.

Grubbs FE [1969]. Procedures for detecting outlying observations in samples. Technometrics *11*(1):1–21, http://www.tandfonline.com/doi/pdf/10.1080/00401706.1969.10490657?needAccess=true

Zhuang Z, Coffey CC, Campbell DL, Myers WR [1998]. Comparison of two newly developed methods for fit testing N95 respirators. J Int Soc Respir Prot *16*(1–4):37–47.