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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 84**

[Docket No. CDC-2013-0017; NIOSH-250]

**Development of Inward Leakage Standards for Half-Mask Air-Purifying Particulate Respirators**

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Request for comment and notice of public meeting.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces a public meeting concerning inward leakage performance requirements for the class of NIOSH-certified non-powered air-purifying particulate respirators approved as half-facepiece respirators for protection from particulate-only hazards. The purpose of this meeting is to share information and to seek stakeholder feedback, in identified topic areas, concerning the development of inward leakage performance standards. Questions concerning the identified topics of specific interest are included in this document. Attendance at the public meeting is not required to submit written responses to the questions in this notice.

**DATES:** The public meeting will be held September 17, 2013, 1:00 p.m. - 5:00 p.m. ET, or after the last public commenter has spoken. Stakeholder comments to the questions included in this document must be received by 11:59 p.m. ET on October 18, 2013.

**ADDRESSES:** Meeting location: Bruceton Research Center, NIOSH National Personal Protective Technology Laboratory (NPPTL), 626 Cochran Mill Road, Building 140, Multi-purpose Room, Pittsburgh, PA 15236. This meeting will also be available by remote access.

Written Comments: You may submit comments by either of the following methods:

- Federal eRulemaking Portal:  
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2013-0017; NIOSH-250). All relevant comments, including any personal information

provided, will be posted without change to

<http://www.regulations.gov>.

Docket: For access to the docket to read background

documents and submitted comments, go to

<http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Colleen Miller, NIOSH  
National Personal Protective Technology Laboratory (NPPTL),  
626 Cochrans Mill Road, Pittsburgh, PA 15236 (412) 386-4956  
or (412)386-5200 (these are not toll free numbers).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Testing, quality control, and other requirements under 42 CFR Part 84 are intended to ensure that respirators supplied to U.S. workers provide effective protection when properly employed within a complete respiratory protection program, as specified under MSHA and OSHA regulations.

NIOSH requirements governing approval of half-mask air-purifying particulate respirators, those defined in this notice, are principally specified in Part 84, under Subpart K--Non-Powered Air-Purifying Particulate Respirators. The performance of the respirator's facepiece-to-face seal and

other potential sources of inward leakage for this type of respirator are important to determine how much unfiltered contaminated air the worker might inhale. The facepiece-to-face seal leakage can be substantial in the case of a poorly fitting respirator. Effective fit testing technology and procedures exist to ensure that half-mask respirators approved by NIOSH under Subpart K of Part 84 have adequately performing facepiece-to-face seals. The purpose of this notice is to solicit stakeholder feedback regarding standards for inward leakage testing.

NIOSH believes that the employee is more likely to achieve a good fit from a respirator design that has been demonstrated to achieve a specified minimum level of performance during certification testing. Accordingly, NIOSH initiated rulemaking activities to establish inward leakage performance requirements for NIOSH-approved particulate filtering respirators by publishing a notice of proposed rulemaking (NPRM) in the **Federal Register** on October 30, 2009 [74 FR 56141]. The public comment period for the rulemaking closed originally on December 28, 2009 but was subsequently extended upon request by stakeholders to September 30, 2010. Public meetings were held on December 3, 2009 and July 29, 2010 to allow stakeholders to share feedback on the proposed rule, including preliminary

results of their independently completed or ongoing research. NIOSH reviewed all comments submitted by stakeholders and is considering them in the development of a revised inward leakage standard.

## **II. Test Panel History**

Although NIOSH requires adequate facepiece-to-face seals for other types of respirators under Part 84, such requirements have not been applied to the half-mask air-purifying particulate respirators approved under subpart K. A new test panel, based on the bivariate distribution of face width and face length, was developed by NIOSH in 2007, based on research completed in 2003.<sup>1</sup> The bivariate panel was developed following an anthropometric survey of 3,997 respirator users to better represent the U.S. civilian workforce by weighting subjects to match the age and race distribution of the U.S. population as determined from the 2000 census. In the rulemaking published in October 2009, NIOSH proposed to incorporate the bivariate panel into the standard testing procedures for inward leakage testing of

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<sup>1</sup> Zhuang Z, Bradtmiller B, and Shaffer R.E. New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce. *Journal of Occupational and Environmental Hygiene* 2007;4:647-659.

these respirators.<sup>2</sup>

In response to stakeholder comments, specifically those addressing concerns about the potential for inter-panel variability when comparing panels comprising different test subjects, NIOSH researchers developed a peer-reviewed protocol to investigate the inter-panel variability. The study began in July 2012 and was recently completed. Data analysis is ongoing and public webinars to share preliminary results were held on July 23, 2013 and August 20, 2013.<sup>3</sup>

During the inter-panel variability study, potential issues with the implementation of the proposed performance requirement were carefully considered by NIOSH leadership, researchers, standard and policy developers, and the technical experts responsible for NIOSH certification testing. This **Federal Register** notice includes questions for stakeholders to better understand and resolve potential implementation issues.

### **III. Public Meeting**

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<sup>2</sup> NIOSH. Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators. Procedure No. RCT-APR-STP-0068. Available at <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-137/0137-081209-DraftTIL.pdf>.

<sup>3</sup> Presentation slides for both webinars are found in the dockets for this action.

NIOSH will hold a public meeting on September 17, 2013 to discuss the development of inward leakage performance standards for the class of NIOSH-certified, non-powered half-facepiece respirators approved under the provisions of Subpart K of 42 CFR Part 84. The format of the meeting will be informal to encourage stakeholders to share information and responses regarding the information presented by NIOSH, the questions included in this notice, and any questions that may be identified during the meeting.

This meeting will also be using Audio/LiveMeeting Conferencing remote access capabilities so that interested parties may listen in and view the presentations simultaneously over the Internet. Parties remotely accessing the meeting will have the opportunity to comment during the open comment period.

Registration is required for both in-person and video conferencing participation. Because this meeting is being held at a Federal site, preregistration is required on or before September 10, 2013 and a government-issued photo ID will be required to obtain entrance to the facility. Non-U.S. citizens must register on or before August 30, 2013 to allow sufficient time for mandatory facility security clearance procedures to be completed. Non-U.S. citizens registered for another meeting at the site on September 17, 2013, will

be considered to be registered for this meeting. NIOSH encourages all others to attend remotely.

An email confirming registration will be sent from NIOSH for both in-person participation and video conferencing participation. Information regarding participation via the video conferencing will be provided in a separate email. This option will be available to participants on a first come, first served basis.

Registration information is available on the NIOSH NPPTL website at <http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/1ttr-09172013.html>.

#### **IV. Questions for Stakeholders**

##### **A. Inward Leakage Performance Standard Test Method**

1. Which of the following test method(s) would you recommend including in the standard test procedure for an inward leakage performance standard test method: condensation nuclei counter (CNC) with differential mobility analyzer with supplemental aerosol, as needed; or general aerosol in a chamber with a quantitative detection method? Please provide your rationale and information that supports your recommendation including experiences, data,

analyses, studies, published articles, and standard professional practices.

2. In light of published data indicating that particle penetration through the filter media is negligible, in your opinion, if the CNC method is used:

- (a) Is the differential analyzer needed? Explain why or why not, providing your rationale and any supporting data or information, including references or sources of technical expert opinion.
- (b) What other detection method for ambient aerosol could be used? Provide any supporting documents, references, or data.
- (c) Is corn oil an acceptable method for evaluating N-series respirators (those restricted to use in workplaces free of oil aerosols) for certification purposes? Why or why not? Are there issues associated with corn oil degradation of the media during the time required to complete a typical OSHA fit test protocol? Please explain your answer. Would your concerns regarding the effects of corn oil be eliminated if the number of exposures to corn oil (i.e., repeated donnings) is limited? Please explain your answer.

- (d) What additional information or issues should NIOSH consider regarding the use of corn oil as an aerosol challenge during performance testing for filtering facepiece respirators? Please include specific information that supports your recommendation including experiences, data, analyses, studies, published articles, and standard professional practices.

3. Should NIOSH allow the option of multiple inward leakage test methods?

4. Should NIOSH define and establish inward leakage standards for quarter-masks? If you represent a respirator manufacturer, do you currently market quarter-mask respirators? If you are a purchaser, do you currently use quarter-mask respirators? Please include a description of the occupational use of the quarter-mask respirators you are manufacturing or using.

#### B. Subject Test Panels

1. What are the advantages and/or disadvantages of using the NIOSH bivariate panel in assessing the facepiece-to-face seal as a regulatory requirement for respirators?

- (a) What are key implementation issues you foresee and how do you recommend addressing these issues?

(b) Would you support the use of another panel, if so, which one (e.g., Los Alamos National Laboratory (LANL) full-facepiece panel, LANL half-facepiece panel<sup>4</sup>)? Please explain your answer.

2. Which panel(s) is your company currently using to develop new respirator models or to modify existing respirators? Please identify or define the panel (e.g., LANL full-facepiece, LANL half-facepiece, NIOSH bivariate, or Principal Component Analysis (PCA)), the number of test subjects generally used, the distribution of the subjects within the panel cells, the sizing basis, and the representation of male and female test subjects. What pass/fail criteria are you currently using to approve proto-types for further development or production?

(a) As a manufacturer, do you use facepiece-to-face seal criteria to qualify a design for production? Please include details about the criteria in your answer.

(b) As a purchaser, what are the attributes you use to determine which brand(s) or model(s) of

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<sup>4</sup> Use of the LANL panels is established in Procedure No. TEB-APR-STP-0005-05a-06, Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit, Air-Purifying Respirators. Available at <http://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0005-05a-06.pdf>.

respirators to buy (e.g., price point, size, supplier, availability)?

3. Does your company use a panel or portion of a panel to develop respirators for a defined user group (e.g., users with smaller facial features, users with larger facial features)? If so, please define the user group, the panel used, the cells included, and the number of subjects generally needed.

(a) Could the LANL half-facepiece panel be used to test respirators for defined user groups? Please explain why or why not and include related implementation issues.

(b) What issues do you foresee in the implementation of fit testing standards for defined user groups?

4. Does your company use a panel or a portion of a panel to ensure the quality of a manufactured product line? If so, what test method and panel are used? How many subjects are included? Please explain how you maintain your pool of subjects.

5. NIOSH currently uses the LANL half-facepiece panel (lip length, which is actually the lip width, and face length) for categorizing human subjects to evaluate those half-mask respirators evaluated for fit. What are the advantages and/or disadvantages of using the LANL half-

facepiece panel for an inward leakage requirement for half-mask air-purifying particulate respirators, approved under subpart K, which are currently not evaluated for fit?

6. What panel size would be sufficient for conducting a facepiece-to-face seal certification test?

- (a) Given the recommended number of test subjects, should the pass/fail criteria be specific and include a minimum of one pass per member cell? More than one per cell?
- (b) Given the recommended number of test subjects, should the pass/fail criteria be panel based (e.g., 20/25, 28/35) and not specific to panel cells?
- (c) Should the pass/fail criteria require an overall high pass rate and allow for a percentage of failures or a lower fit factor pass criteria and a 100 percent pass rate?

C. Future Utility of the NIOSH Bivariate Panel for All NIOSH-Approved Respirators

1. Based on your experience with the NIOSH bivariate panel, what implementation issues must NIOSH consider in order to use the NIOSH bivariate panel for certification testing of all classes of respirators?

2. Should NIOSH develop a second NIOSH bivariate panel based on face length and lip length? Please explain why or why not and any implementation concerns or specific recommendations concerning future implementation of a new panel utilizing subject lip length and face length.

D. Inter-Panel Variability

1. What is an appropriate pass/fail criterion? Assuming the CNC is used, should the subject pass with a fit factor of 20? 50? 75? 100?

2. If a corn oil chamber is used, what inward leakage pass/fail criteria should be used?

3. What other strategies do you suggest to address the inter-panel variability? Please provide specific information that supports your recommendation including experiences, data, analyses, studies, published articles, and standard professional practices.

Dated: August 27, 2013.

Kathleen Sebelius  
Secretary

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