Miller, Diane M. (CDC/NIOSH/EID)

From: Gardner, Paul D ECBC [paul.gardner2@us.army.mil]
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Subject comments are attached in both MS Word and Adobe pdf file formats.

Paul Gardner
Team Leader, Respiratory Protection Team
US Army RDECOM
Edgewood Chemical Biological Center
410.436.6692
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MEMORANDUM FOR RECORD

TO: NIOSH Docket Officer

SUBJECT: Comments to NIOSH Total Inward Leakage Program for Certification of Particulate Half-Mask Respirators

REFERENCE DOCKET #: TIL-NIOSH 036

SUBMITTED BY: Paul Gardner and Jonathan Eshbaugh
U.S. Army Edgewood Chemical Biological Center
Attn: AMSRD-ECB-RT-PR\Bldg E5604
Aberdeen Proving Ground, MD 21010-5424
e-mail: paul.gardner2@us.army.mil
phone: 410.436.6692

1. Background.

The NIOSH proposes to develop a Total Inward Leakage (TIL) test as part of its respirator certification program. Initially, TIL testing will be required for the certification of particulate half-mask air-purifying respirators.[1] As stated in the 17 January 2007 Technical Concept, the TIL test is intended to quantify the ability of respirators to fit a range of individuals; it is not intended to replace individual fit testing as mandated by OSHA.[2]

The proposed TIL method is intended to measure the particulate aerosol concentration within the respirator mask as a result of face seal leakage, not filter penetration. The TIL is calculated in terms of a percent penetration by measuring the aerosol concentration inside and outside of the respirator mask. The test assumes that all particles detected within the respirator mask are the result of face seal leakage. Hence, the particulate penetration of the mask filter element and other components (for example, the exhalation valve) is assumed to be negligible.

2. Proposed NIOSH TIL Test Method.

The PortaCount Plus (Model 8020, TSI, Shoreview, MN) in combination with the N95-Companion (Model 8095, TSI, Shoreview, MN) is proposed for TIL testing. The PortaCount Plus is a condensation nucleus counter that grows and counts particles from the challenge and mask atmospheres. The N95-Companion is an electrostatic classifier that only lets particles within a target size range (approximately 25 - 60 nm) through the sample stream to be counted by the PortaCount.[3]

3. Most Penetrating Particle Size.

Particle penetration through air filter media is dependent on several parameters including face velocity (a function of flow rate and available surface area), challenge particle size, and several filter properties including the thickness, fiber diameter, and fiber packing density. The most penetrating particle size (MPPS) is dependent mostly on the filter properties and to a lesser extent, the flow rate. The MPPS generally occurs between 50 and 500 nm.[4]

Single fiber filtration theory predicts a MPPS of approximately 100 to 300 nm.[4] According to the single fiber theory, particles smaller than 100 nm are thus expected to be filtered more efficiently. An application note (ITI-053) published by TSI on the N95-Companion device appears to support this assumption by providing data that shows the MPPS of "typical" 95 category filters in the range of 150 and 200 nm.[3] However, the source of this data is not provided. TSI erroneously concludes that: "Without the N95-Companion, the discarded particles [particles <25 nm and >60 nm] could be incorrectly counted as face seal leakage, because many of them are in the size range that can penetrate an N95 filter."

Unfortunately, the single fiber filtration theory that predicts a MPPS of 100 to 300 nm does not take into account the electrostatic forces used to capture particles in state-of-the-art N95 filters. It only accounts for diffusion, interception, and impaction (the three main forces that contribute to mechanical filtration). Most N95 filters use electrostatic forces in addition to the other three forces to improve filtration efficiency and decrease breathing resistance.

Several studies have shown that the MPPS is approximately 40-50 nm for most N95 filters at flow rates below 85 L/min.[5,6,7] Richardson et. al. (2006) found that the MPPS for several N95 cartridges and filtering facepieces was generally between 50 and 100 nm for N95 half-mask filters and filtering facepieces.[5] In a recent study performed at NPPTL by Rengasamy et. al., (2007), the MPPS measured through five NIOSH-approved N95 filters occurred at 40 nm.[6] Likewise, Balazy et. al., (2005) evaluated two N95 facepiece respirators and found the MPPS to be between 30 and 70 nm at 30 and 85 L/min.[7]

4. Conclusion.

The above research provides evidence that penetration will occur in N95 filters during fit testing when challenged with particles within the 25 to 60 nm range. Since there is no way to distinguish between particles that penetrate the filter element or leak through the mask seal, the proposed method using the PortaCount Plus and N95-Companion could result in artificially high TIL values. The TIL results for N95 respirators would therefore be biased towards lower than expected protection levels due to the potential of filter penetration of the challenge aerosol. Even under the relatively low breathing flow conditions

associated with the proposed fit test exercise routine (estimated to be < 25 L/min), the bias could be significant.

Alternatively, respirators that use filters that rely solely on mechanical capture mechanisms would have a MPPS between 100 and 300 nm. Commercial P100 filters have been shown to have a MPPS ranging from 100 to 200 nm.[5] Most P100 filters are very efficient at removing particles in their MPPS size range and the smaller 25 to 60 nm size range produced by the N95-Companion. The small amount of particulate filter penetration predicted in the N95-Companion challenge size range is not likely to significantly affect the TIL measurement, especially taking into account the relatively low NIOSH proposed pass/fail criterion level of 0.5%. Thus, the particulate concentration measured inside a given P100 mask using the proposed method would most likely result in a reasonably unbiased TIL calculation.

5. Recommendation.

To prevent potential N95 particulate respirator TIL measurement biases, we recommend that a suitable challenge aerosol approved for human subject testing, such as corn oil or poly alpha olefin, be generated that has a count medium diameter in the 400 to 600 nm range similar to that used in the Laboratory Respirator Protection Level (LRPL) test for certifying CBRN respirators.[8] This size range is well over the MPPS of all classes of particulate respirator filters and small enough to effectively penetrate the face seal without significant particle losses.[9,10] A polydisperse challenge aerosol in this size range can be easily generated with the proper nebulizer at a concentration that is compatible with the measurement range of the PortaCount Plus. Alternatively, a higher concentration could be generated and a light-scattering photometer used for the aerosol measurement device as described in the LRPL standard testing procedure.[8] Another possible option would be to have the manufacturer modify the N95-Companion to select larger challenge particles, for example in the 200 to 400 nm size range, to minimize the potential for particulate penetration through the filter element.

/s/

Paul Gardner
Team Leader
Respiratory Protection Team
R&T Directorate, ECBC

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