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- 1 Flammability of Respirators and other Head and Facial Personal Protective Equipment ... *Samy Rengasamy, George Niezgodá, and Ron Shaffer*
- 14 Utility of an Optical Particle Counting Instrument for Quantitative Respirator Fit Testing with N95 Filtering Facepieces ... *Bingbing Wu, Maija Leppänen, Michael Yermakov, and Sergey A. Grinshpun*
- 26 Feasibility Assessment of a New Surveillance Tool for Respiratory Protective Devices Used in U.S. Healthcare ... *Kerri Wizner, Lewis Radonovich, Allie Bell, Charles Oke, Mary Yarbrough*
- 36 History of U.S. Respirator Approval ... *David Spelce, Timothy R Rehak, Richard W. Metzler, and James S. Johnson*
- 47 Evaluation of a Shortened Qualitative Fit Test Method for Filtering Facpiece Respirators ... *Rhiannon Mogridge, Alison Bowry, Mike Clayton*
- 65 2018 ISRP conference program
- 71 Instructions for Authors



Flammability of Respirators and other Head and Facial Personal Protective Equipment

Samy Rengasamy*, George Niezgod, and Ron Shaffer

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania 15236

* Corresponding author and E-mail: rda5@cdc.gov

ABSTRACT

Background: Personal protective equipment (PPE) is worn by workers in surgical settings to protect them and patients. Food and Drug Administration (FDA) clears some PPE (e.g., surgical masks (SM)) as class II medical devices, and regulates some (e.g. surgical head cover) as class I exempt devices. For respiratory protection, National Institute for Occupational Safety and Health (NIOSH)-approved N95 filtering facepiece respirators (FFRs), and powered air-purifying respirators (PAPRs) are used. One type of PPE, “surgical N95 respirators”, is a NIOSH-approved FFR that is also cleared by the FDA for use in medical settings. The surgical environment poses unique risks such as the potential for surgical fires. As part of its substantial equivalence determination process, FDA requests testing of flammability and other parameters for SM and surgical N95 respirators. A lack of data regarding flammability of PPE used in healthcare exists. We hypothesize that commonly used PPE, regardless of whether regulated and/or cleared by FDA or not, will pass an industry standard such as the 16 CFR 1610 flammability test.

Methods: Eleven N95 FFR models, eight surgical N95 respirator models, seven SM models, five surgical head cover models, and five PAPR hood models were evaluated for flammability with a 45 degree flammability tester using the 16 CFR 1610 method. Three common fabrics were included for comparison.

Results: All of the PPE samples regulated/and or cleared by FDA or not, passed the flammability test at class 1 (normal flammability), meaning they are less likely to burn. Only one of the three common fabrics, a cotton fabric at the lowest basis weight, was class 3 (high flammability).

Conclusions: The results obtained in the study suggest that NIOSH-approved N95 FFRs would likely pass the 16 CFR 1610 flammability standard. Moreover, results suggest that NIOSH is capable of undertaking flammability testing using the 16 CFR 1610 standard as the flammability results NIOSH obtained for N95 FFRs were comparable to the results obtained by a third party independent laboratory.

Keywords: Flammability, N95 filtering facepiece, surgical N95 respirator, surgical mask, surgical head cover, powered air-purifying respirator (PAPR) hood, surgery, healthcare

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Utility of an Optical Particle Counting Instrument for Quantitative Respirator Fit Testing with N95 Filtering Facepieces

Bingbing Wu^{1*}, Maija Leppänen^{1,2*}, Michael Yermakov¹, and Sergey A. Grinshpun^{1#}

¹ Center for Health-Related Aerosol Studies, Department of Environmental Health, University of Cincinnati, PO Box 670056, Cincinnati, OH 45267-0056, USA

² On leave from University of Eastern Finland, Department of Environmental and Biological Sciences, PO Box 1627, 70211 Kuopio, Finland

* Equal contributions

Corresponding author and E-mail: sergey.grinshpun@uc.edu

ABSTRACT

Currently, the aerosol-based quantitative respirator fit testing is primarily conducted using a PortaCount® (TSI Inc., Shoreview, MN, USA), which utilizes a condensation particle counting (CPC) technique and measures particles in a size range of $d_p \sim 0.02 - 1 \mu\text{m}$. A U.S. OSHA-accepted fit testing protocol or similar protocols approved by other countries' regulatory agencies shall be followed. We recently investigated a new instrument, MT-05U (Sibata Scientific Technologies, Ltd., Tokyo, Japan) utilizing an optical particle counting (OPC) technique, $d_p \geq 0.3 \mu\text{m}$, for the quantitative fit testing of three types of respirators with high-efficiency filters – the P100 filtering facepiece respirators (FFRs), and elastomeric half- and full-face respirators. Conducted with the PortaCount® as the reference instrument, good feasibility of the OPC method for fit testing of the above-mentioned types of respirators was demonstrated, according to the ANSI standard Z88.10-2010. The present effort is a follow-up study, in which the same fit testing instrument MT-05U was evaluated utilizing the same approach for N95 FFRs via the PortaCount® N95-Companion™ as the reference instrument. It was found that the new instrument could identify inadequate fits of all tested N95 FFRs with sensitivity (probability of identifying inadequate fits) of 1.00, exceeding the ANSI mandatory requirement of ≥ 0.95 . The predictive value of a pass was 1.00 as well, exceeding the advisory criteria of ≥ 0.95 . Additionally, the specificity and predictive value of a fail were 0.59 and 0.69, respectively, both exceeding the advisory criteria of ≥ 0.5 . The value of the kappa statistic was 0.58 falling below the threshold of 0.7 (it is acknowledged though that the latter is optional as it is neither mandatory nor advised according to ANSI). In conclusion, the evaluated OPC-based fit tester could be successfully deployed as an alternative method for quantitative fit testing for N95 FFRs.

Keywords: N95 respirator, fit test, optical particle counter, condensation particle counter

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Feasibility Assessment of a New Surveillance Tool for Respiratory Protective Devices Used in U.S. Healthcare

Kerri Wizner ^{*1,2}, Lewis Radonovich¹, Allie Bell,³ Charles Oke¹, Mary Yarbrough³

¹ National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA

² Association of Schools and Programs of Public Health, Washington DC

³ Vanderbilt University, Department of Health and Wellness, Nashville, TN

* Corresponding author and E-mail: ytm3@cdc.gov

ABSTRACT

Background: Respiratory protective devices (RPDs) are used for infection prevention in healthcare settings during routine patient care and public health emergencies. In recent years, healthcare systems have experienced shortages of RPDs during outbreaks of infectious diseases, in part due to a lack of information about their availability. New tools to track RPD inventories may improve accessibility during an emergency. Investigators at Vanderbilt University have identified four major themes that influence RPD use for infection prevention: hospital preparedness, responsiveness to airborne pathogens, potential exposure outcomes, and infection control practices related to respirator effectiveness. Based on these findings, an RPD surveillance tool (RST) was developed to collect and share near real-time data about RPD supplies in healthcare facilities. The objective of this study was to conduct a feasibility assessment of this RST.

Methods: The new online surveillance tool was implemented at four large, urban, acute care U.S. hospitals in January 2014; data was collected about RPD inventory, tracking systems, hospital characteristics, and utility of gathered information.

Results: The RST was implemented successfully and without difficulty at hospitals that had 78 to 90 percent occupancy rates. Participating hospitals reported that the RST (1) provided value for benchmarking their RPD supply, (2) promoted understanding about RPD accessibility among hospital systems engaged in infection control, and (3) served as a means to assess RPD program quality.

Conclusion: Implementation of this newly developed RST is feasible and appears to have utility in U.S. hospitals for tracking and understanding RPD use for routine healthcare delivery and public health emergencies.

Keywords: Respirator use and supply; Respiratory protective devices (RPDs); Feasibility assessment; Hospital setting; PPE surveillance system; Respiratory protective device surveillance tool (RST)

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History of U.S. Respirator Approval

David Spelce¹, Timothy R Rehak², Richard W. Metzler³, and James S. Johnson⁴

¹ 921 LeShea Court, Chesapeake, VA

² National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA

³ Richard W. Metzler Inc., 810 Longvue Drive, Houston PA

⁴ JSJ and Associates, 7867 Cypress Creek Court, Pleasanton, CA

Corresponding author E-mail: Spelce@cox.net

ABSTRACT

This article is the second in a series of four articles on respirator history. The discussions presented in this article follow the history of respirator requirements, use, improvements, and certification in America. Included is a discussion of respirator evolution prior to American certification standards and discussion of the need, primarily from the mining industry, for government respirator certification. The reasons for government intervention and the origination of the American respirator certification program are discussed.

Keywords: respirator certification history; respiratory protection.

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Evaluation of a Shortened Qualitative Fit Test Method for Filtering Facepiece Respirators

Rhiannon Mogridge^{1*}, Alison Bowry¹, Mike Clayton^{1,2}

¹ Health and Safety Executive, Harpur Hill, Buxton, SK17 9JN, UK

² Change of address since completion of this work: 3M Centre, Cain Road, Bracknell, Berkshire, RG12 8HT, UK

* Corresponding author and E-mail: rhiannon.mogridge@hsl.gsi.gov.uk

ABSTRACT

The most commonly used type of respiratory protective equipment (RPE) in the healthcare sector in Great Britain (GB) is the disposable filtering facepiece. As a type of tight-fitting respirator, the Health and Safety Executive's guidance requires that fit testing be carried out as part of the selection process. The GB healthcare industry typically employs the qualitative fit testing method. If a shortened qualitative fit test protocol could be validated, its use could help to reduce overall time investment required for an effective fit testing programme.

A shortened qualitative fit test method (duration approximately 2 minutes) was compared against a generated aerosol quantitative fit test method using the approach given in the American National Standards Institute (ANSI) standard Z88.10-2010 Annex 2 *Criteria for Evaluating New Fit Tests Methods*.

Results show that the shortened qualitative fit test method failed to meet the evaluation criteria of ANSI Z88.10. The *test sensitivity*, which gives the probability of the shortened qualitative fit test method failing a mask that is a poor fit, was 0.70, which is less than the requirement of ≥ 0.95 . The value of 0.70 means that 70% of poor fits would be expected to fail the shortened qualitative fit test method (true failures). Conversely, 30% of poor fits would be expected to pass the shortened qualitative fit test method (false passes). The shortened qualitative fit test method is therefore likely to produce a higher proportion of false passes, potentially leading to a reduction in protection than that expected from this type of RPE.

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Keywords: Respiratory protective equipment (RPE), respirator fit test, qualitative fit test, quantitative fit test, Bitrex, PortaCount, filtering facepiece respirator

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