FINAL PERFORMANCE REPORT

for

NIOSH GRANT 5 RO1 OH02948

"PERFORMANCE OF SURGICAL MASKS"

Principal Investigator: Klaus Willeke, Ph.D., CIH
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No-cost Extension through 08/31/95
Total Direct Costs Year 1: $91,496
Total Direct Costs Year 2: $96,241

June 29, 1995

Report is prepared along the Option 2 guidelines of the Oct 27, 1994 memorandum entitled "Assistance Award Closeout Requirements"

NOTE

The original grant request was for three years of study. The grant was funded for two years at about half the originally requested amount per year. The Revision of February 16, 1992 reduced the originally stated Specific Aims 1 - 4 to minor foci, but maintained the essential parts of Specific Aims 5 -7. The request of February 16, 1994 to reinstate $12,300 into the budget for a differential interference microscope attachment, needed to perform the work for Specific Aim 7, was denied.

Prior to this grant, Klaus Willeke performed related work under NIOSH Grant OH01301 "New Methods for Quantitative Respirator Fit Testing". In 1994 Klaus Willeke and co-authors Chih Chieh Chen (formerly Ph.D. student, now Associate Professor at National Taiwan University) and Matti Lehtimäki (formerly visiting scientist from Finland) received the "Best Aerosol Paper Award" at the American Industrial Hygiene Conference and Exposition in Anaheim, California, for their AIHAJ paper entitled "Loading and Filtration Characteristics of Filtering Facepieces." Klaus Willeke was also the recipient of the same award during the previous year with an AIHAJ paper co-authored by NIOSH colleagues William Heitbrink (PH.D. thesis) and Paul Baron (co-author of this and several other papers and one book). Former Ph.D. student Dennis O'Brien has recently been named Director of the Physical Science and Engineering Division at NIOSH -Cincinnati.

LIST OF PUBLICATIONS

Journal Articles

Willeke K, Quian Y, Donnelly J, Grinshpun S, Ulevicius: Penetration of Airborne Microorganisms through a Surgical Mask and a Dust/Mist Respirator. *Am Ind Hyg Assoc J.* Revised Manuscript to be accepted in August or September 1995

Chang C W, Grinshpun S A, Willeke K, Macher J, Donnelly J, Clark S, Juozaitis A: Factors Affecting Microbial Colony Count Accuracy for Bioaerosol Sampling and Analysis, *American Industrial Hygiene Association Journal*, accepted (1995).

Myojo T, Willeke K, Chen CC: Fit Test for Filtering Facepieces: Search for a Low-Cost, Quantitative Method. *Am Ind Hyg Assoc J* 55(9): 797-805 1994

Willeke K, Grinshpun S, Quian Y, Donnelly J, Juozaitis A, Ulevicius V: Physical and Biological Aerosol Penetration and Face-Seal Leak Characteristics of Industrial and Health-Care Respirators. *J Aerosol Sci* 25: S569-S570, 1994

Weber A, Willeke K, Marchioni R, Myojo T, McKay R, Donnelly J, Liebhaber F: Aerosol Penetration and Leakage Characteristics of Masks used in the Health Care Industry. *Am J Infection Control 21* (4) : 167-173, 1993

Willeke K, Chen CC, Myojo T, Weber A, Krishnan U, Juozaitis A, Marchioni R, Lehtimäki M: Filtration, Loading and Faceseal Leakage Characteristics of Filtering Facepieces. *J Aerosol Sci*, 23:S749-S752, 1992

Proceedings

Quian Y, Willeke K, Donnelly J, Grinshpun SA, Juozaitis A: Health-Care Mask Penetration by Microorganisms Similar in Shape to Tuberculosis Bacteria. Presentation Abstract 265. Am Ind Hyg Conference & Exposition, Anaheim, CA, May 1994

Willeke K, Grinshpun SA, Quian Y, Donnelly J, Terzieva S, Ulevicius V: Performance of Health-Care Masks/Respirators against Airborne Microorganisms. Poster Abstract 257. Assoc for Professionals in Infection Control and Epidemiology Annual Meeting, Cincinnati, OH, May 1994

Willeke K, Quian Y, Grinshpun S, Donnelly S, Terzieva S, Juozaitis A, Ulevicius V: Aerosol Penetration through Health-Care Respirators. Presentation Abstract, Vol 1, pp 146-147, Fourth International Aerosol Conference, Los Angeles, CA, Sept 1994

Qian Y, Juozaitis A, Donnelly J, Grinshpun SA, Kalatoor S, Willeke K: Experimental Evaluation of the Surgical Mask Penetration Characteristics Using Biological and Non-Biological Particles. Abstract 3A5. American Association for Aerosol Research Meeting, Oak Brook, IL Oct 1993

SIGNIFICANT FINDINGS

Surgical mask evaluations with inert particles have shown a considerable range in collection efficiency values depending on the mask tested. Penetration is highest for submicrometer-sized aerosols, approaching 100% for some masks used. Some industrially used dust-mist-fume respirators have less penetration than the best currently used surgical mask. However, in the presence of a large face-seal leak, the dust-mist-fume mask may not provide any more protection than a surgical mask with a lower filtration efficiency. Due to the higher pressure drop across the dust-mist-fume mask it may even perform worse than the surgical mask, because considerable aerosol flow may be directed through the leak site. Thus, it is concluded that improvements in filtration efficiency in health care masks may necessitate quantitative fit testing to ensure proper fit of the mask to the health care worker's face.

The concentrations of bacteria upstream and downstream of the health-care respirators were measured with an Aerosizer, a relatively new aerodynamic size spectrometer, which was found to effectively and dynamically measure the bacterial concentration over the entire bacterial size range down to 0.5 μm in aerodynamic size. The results indicate that spherical *Streptococcus salivarius* bacteria have the same penetration efficiency in the size range from 0.9 to 1.7 μm as traditionally used inert corn oil test particles. Rod shaped bacteria penetrate less. The penetration difference between the spherical and rod-shaped bacteria depends on the ratio of the length to the diameter of the bacteria. If this aspect ratio is 3 to 4, typical of many bacteria including *Mycobacterium tuberculosis* bacteria (MTB), the penetration of these elongated bacteria is about half that of spherical ones. Thus, a respirator that collects 95% of rod-shaped microorganisms with an aspect ratio of 3 to 4 collects only about 90% of spherical microorganisms or test particles.

USEFULNESS OF FINDINGS

Workers in various industries, such as health-care facilities and waste process plants, are potentially exposed to infectious aerosols, e.g. *Mycobacterium tuberculosis* bacteria (MTB). Recent regulations require better protection than previously considered adequate. This research has shown that higher efficiency filters in health care masks will provide better protection provided there is an adequate face seal fit of the mask to the wearer's face. Thus, fit testing regulations should be considered for health care environments, similar to those already in place for other occupational work environments.

The 1993 Draft Guidelines by the Centers for Disease Control (CDC) require "the ability to filter particles 1 micron in size in the unloaded state with a filter efficiency of >95 %, given flow rates of up to 50 liters per minute." The 1994 notice of the proposed rule making by the National Institute for Occupational Safety and Health (NIOSH) proposes that new particulate filters meet or exceed the performance recommendation contained in the 1993 CDC document. This research has shown that it is necessary to define the physical shape of the 1 micron test particle. A filter

through which 5 % of spherical test particles penetrate will have only 2.5 to 3 % of rod-shaped microorganisms penetrate if their aspect (length to diameter) ratio is 3 to 4, as is the case for MTB. A filter that is 95 % efficient against spherical test particles is therefore projected to be 97 to 97.5 % efficient against MTB, i.e. greater protection is provided against rod-shaped than spherical bacteria. Conversely, if the regulation is intended to require 95 % efficiency against rod-shaped bacteria such as MTB, a respirator with only about 90 % efficiency against spherical test particles or microorganisms is needed.

ABSTRACT

The objective of this research was to study the performance of masks and respirators currently used or considered for use in the health care industry. The principal aim was to determine to what degree the collection efficiencies obtained with bacteria differ from those obtained by the use of inert, non-viable test particles currently used to evaluate industrial masks and respirators.

It was found that higher efficiency filters in health care masks will provide better protection provided there is an adequate face seal fit of the mask to the wearer's face. In the presence of a large face-seal leak, a higher performance mask may perform worse than a less efficient mask, because the higher pressure drop across the higher performance mask will direct more air flow through the face seal leak. Thus, fit testing regulations should be considered for health care environments, similar to those already in place for other occupational work environments.

The concentrations of bacteria upstream and downstream of the health-care respirators were measured with an Aerosizer, a relatively new aerodynamic size spectrometer, which was found to effectively and dynamically measure the bacterial concentration over the entire bacterial size range down to 0.5 μm in aerodynamic size. The results indicate that spherical *Streptococcus salivarius* bacteria have the same penetration efficiency in the size range from 0.9 to 1.7 μm as traditionally used inert corn oil test particles. Rod shaped bacteria penetrate less. The penetration difference between the spherical and rod-shaped bacteria depends on the ratio of the length to the diameter of the bacteria. If this aspect ratio is 3 to 4, typical of many bacteria including *Mycobacterium tuberculosis* bacteria (MTB), the penetration of these elongated bacteria is about half that of spherical ones. Thus, a filter that is 95 % efficient against spherical test particles is projected to be 97 to 97.5 % efficient against MTB, i.e. greater protection is provided against rod-shaped than spherical bacteria. Conversely, if the regulation is intended to require 95 % efficiency against rod-shaped bacteria such as MTB, a respirator with only about 90 % efficiency against spherical test particles or microorganisms is needed.

RELATIONSHIP OF THE PUBLICATIONS TO THE INDICATED SPECIFIC AIMS

In spite of the significant reductions in budget and time, the essential aims of the original grant proposal have been accomplished. The original grant request was for

three years of study. The grant was funded for two years at about half the originally requested amount per year. The Revision of February 16, 1992 reduced the originally stated Specific Aims 1 - 4 to minor foci, but maintained the essential parts of Specific Aims 5 -7. The request of February 16, 1994 to reinstate $12,300 into the budget for a differential interference microscope attachment, needed to perform the work for Specific Aim 7, was denied.

AIM 1. Performance Measurement with Biologically Inert Aerosols.

This aim has been satisfied by the following journal publication, with support credit given to OH02948 (copy attached):

"Aerosol Penetration and Leakage Characteristics of Masks Used in the Health Care Industry" by A. Weber, K. Willeke, R. Marchioni, T. Myojo, R. McKay, J. Donnelly, and F. Liebhaber. *American Journal of Infection Control 21*, 167 - 173 (1993).

Angela Weber joined NIOSH-Cincinnati after receiving her Master degree with this journal article.

AIM 2. Performance Measurements of Wetted Masks.

This aim was considered less important within the limitations of the reduced grant support and was therefore not performed.

AIM 3. Simultaneous Measurement of Edge Leakage and Filter Penetration. This aim is addressed by the publication quoted under Aim 1 and by the following journal publication:

"Fit Test for Filtering Facepieces: Search for a Low-Cost, Quantitative Method" by T. Myojo, K. Willeke and C.C. Chen, *American Industrial Hygiene Association Journal* 55(9): 797 - 805 (1994).

This journal paper attempts to find a method for measuring simultaneously the filter performance and the face seal leakage where the two leak paths can not be separated in non-cartridge type masks, as used in the health-care industry.

Dr. Myojo is continuing his respirator research at the National Institute of Industrial Health in Kawasaki, Japan.

AIM 4. Differentiation and Modelling of the Filtration Mechanisms.

This aim has been satisfied by the following (award-winning) journal publication, with support credit given to the previous grant OH01301:

"Loading and Filtration Characteristics of Filtering Facepieces" by C.C. Chen, M. Lehtimäki and K. Willeke, *American Industrial Hygiene Association Journal 54*, 51 - 60 (1993).

After receiving his Ph.D., C.C. Chen worked for NIOSH-Cincinnati for two years. Recently he joined, as an Associate Professor, National Taiwan University - School of Public Health in Taipei, Taiwan. He is continuing respirator research there.

AIM 5. Characterization of Sprays Containing Biological Materials.

The Bacterial Filtration Test, developed by Green and Vesley thirty years ago, is no longer needed today for evaluating modern health care masks. Even Dr. Vesley no longer has the setup named after him. We therefore decided that rebuilding an old setup and testing with it will have only minor benefit. Instead, we have tested the aerosolization of solid materials from liquids. A typical test result is shown in Figure 1. The knowledge gained from these tests has allowed us to better disperse biological materials from liquids, and was used to satisfy the next aim. See Aim 6 for resulting publications.

AIM 6. Measurement of Filter Penetration with Bioaerosols.

Three papers on the principal aim of this grant have been published or are about to be published:

Willeke K, Quian Y, Donnelly J, Grinshpun S, Ulevicius: Penetration of Airborne Microorganisms through a Surgical Mask and a Dust/Mist Respirator. *Am Ind Hyg Assoc J.* Revised Manuscript to be accepted in August or September 1995

Willeke K, Grinshpun S, Quian Y, Donnelly J, Juozaitis A, Ulevicius V: Physical and Biological Aerosol Penetration and Face-Seal Leak Characteristics of Industrial and Health-Care Respirators. *J Aerosol Sci* 25: S569-S570, 1994

Willeke K, Chen CC, Myojo T, Weber A, Krishnan U, Juozaitis A, Marchioni R, Lehtimäki M: Filtration, Loading and Faceseal Leakage Characteristics of Filtering Facepieces. *J Aerosol Sci*, 23:S749-S752, 1992

Five figures from the first and most important one of these publications are included as Figures 2 - 6 in this report. They show that the aerosol penetration through respirators may be significantly less than for inert spherical test particles, depending on the complexity of the microorganism.

The accomplishments of this principal aim are also contained in the following Conference Proceedings:

Quian Y, Willeke K, Donnelly J, Grinshpun SA, Juozaitis A: Health-Care Mask Penetration by Microorganisms Similar in Shape to Tuberculosis Bacteria. Presentation Abstract 265. Am Ind Hyg Conference & Exposition, Anaheim, CA, May 1994

Willeke K, Grinshpun SA, Quian Y, Donnelly J, Terzieva S, Ulevicius V: Performance of Health-Care Masks/Respirators against Airborne Microorganisms. Poster Abstract 257. Assoc for Professionals in Infection Control and Epidemiology Annual Meeting, Cincinnati, OH, May 1994

Willeke K, Quian Y, Grinshpun S, Donnelly S, Terzieva S, Juozaitis A, Ulevicius V: Aerosol Penetration through Health-Care Respirators. Presentation Abstract, Vol 1, pp 146-147, Fourth International Aerosol Conference, Los Angeles, CA, Sept 1994

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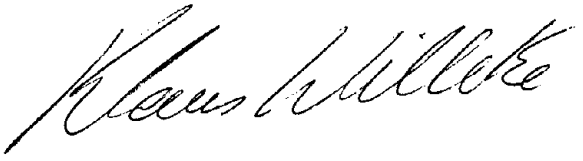
AIM 7. Development of Biological Detection Methods.

The $12,300 for a differential interference microscope attachment, needed to perform this task, was not reinstated in the budget. Therefore, this task could not be performed as planned. However, related work was undertaken on biological detection with partial credit given to this grant:

Chang C W, Grinshpun S A, Willeke K, Macher J, Donnelly J, Clark S, Juozaitis A: Factors Affecting Microbial Colony Count Accuracy for Bioaerosol Sampling and Analysis, *American Industrial Hygiene Association Journal*, accepted (1995).

INVENTIONS

No inventions were claimed under this grant.



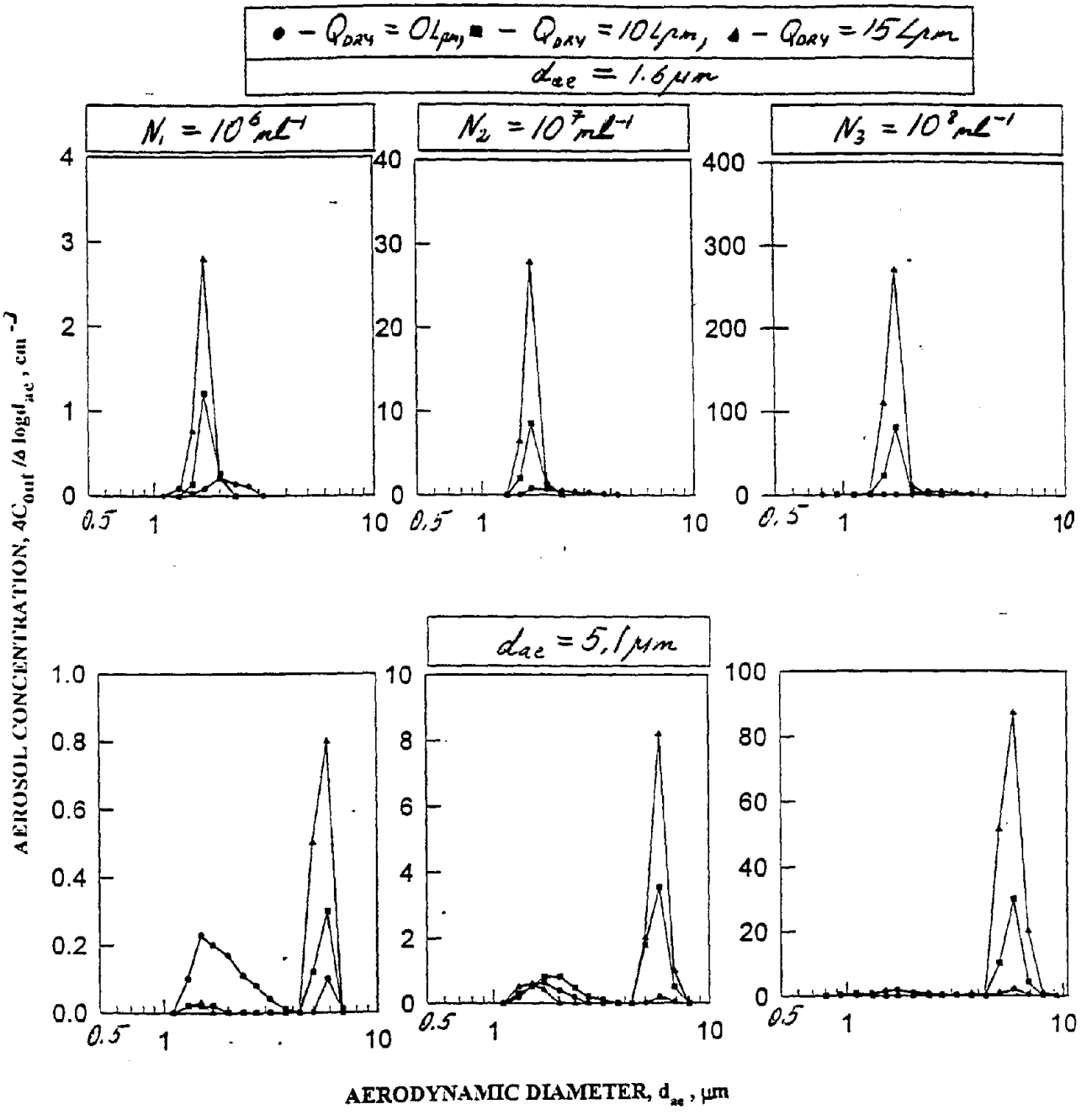


Figure 1. Particle size distributions of aerosolized liquids containing solid materials. Effect of drying on particles of different size and concentration. Q_{dry} = dry air flow rate. N = particle number concentration.

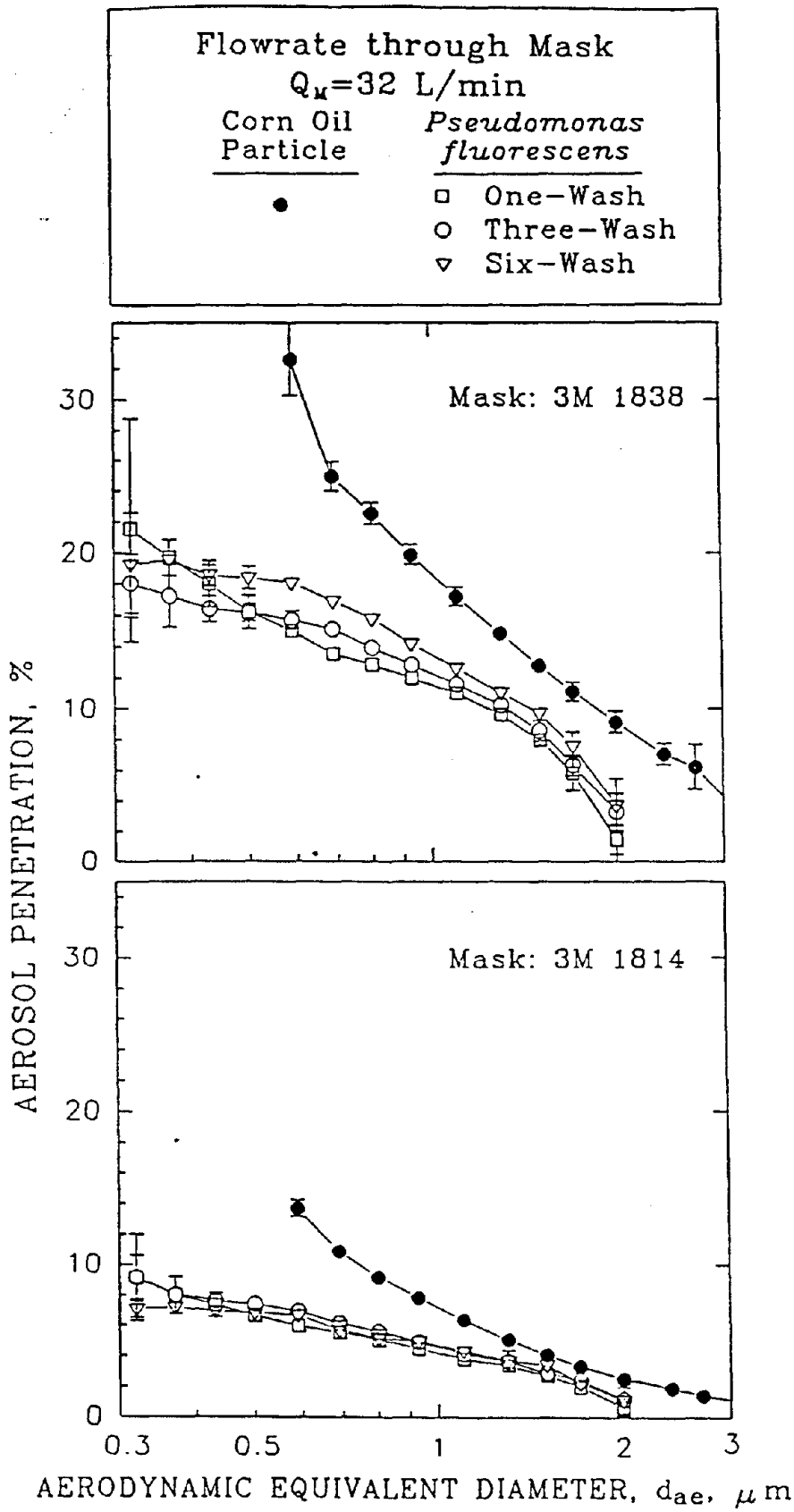


Figure 2. Comparison of bacterial penetration to that with inert, spherical test particles for a flat surgical mask (No.1838 by 3M Company) and a cone-shaped health-care mask (No. 1824 by 3M Company).

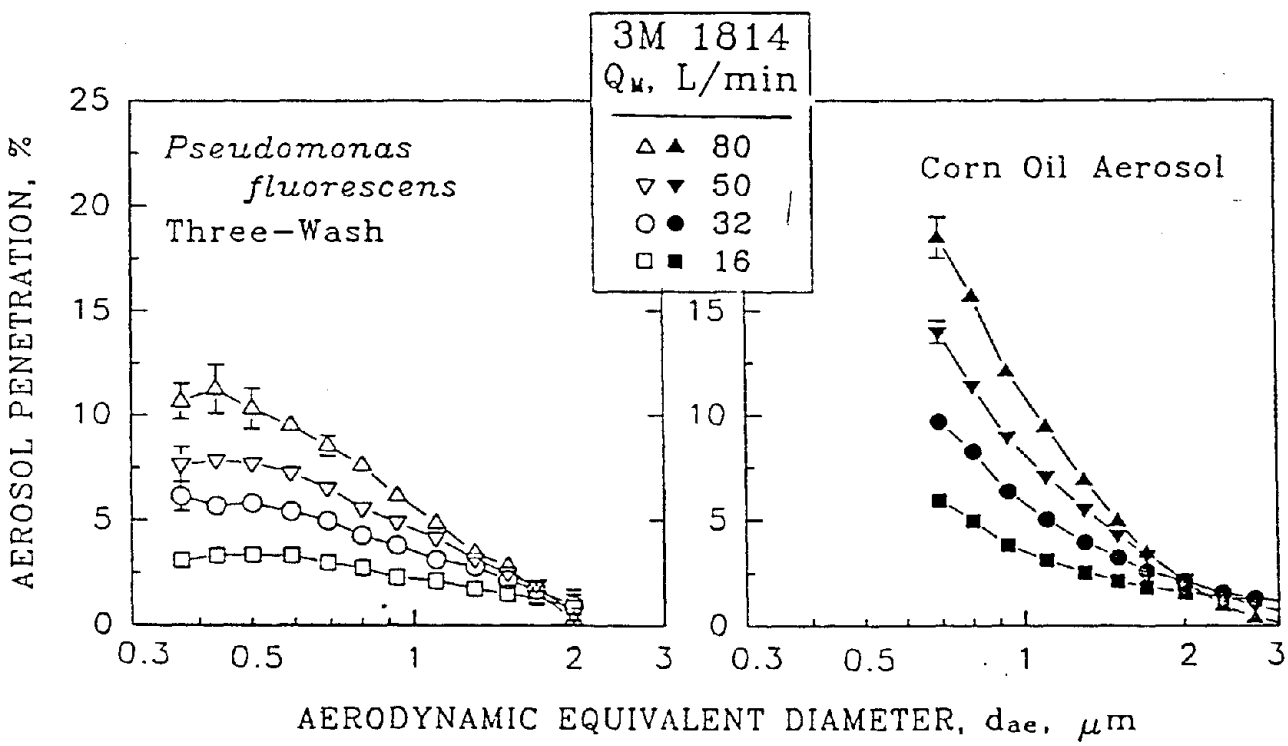


Figure 3. Penetration efficiency as a function of flow rate.

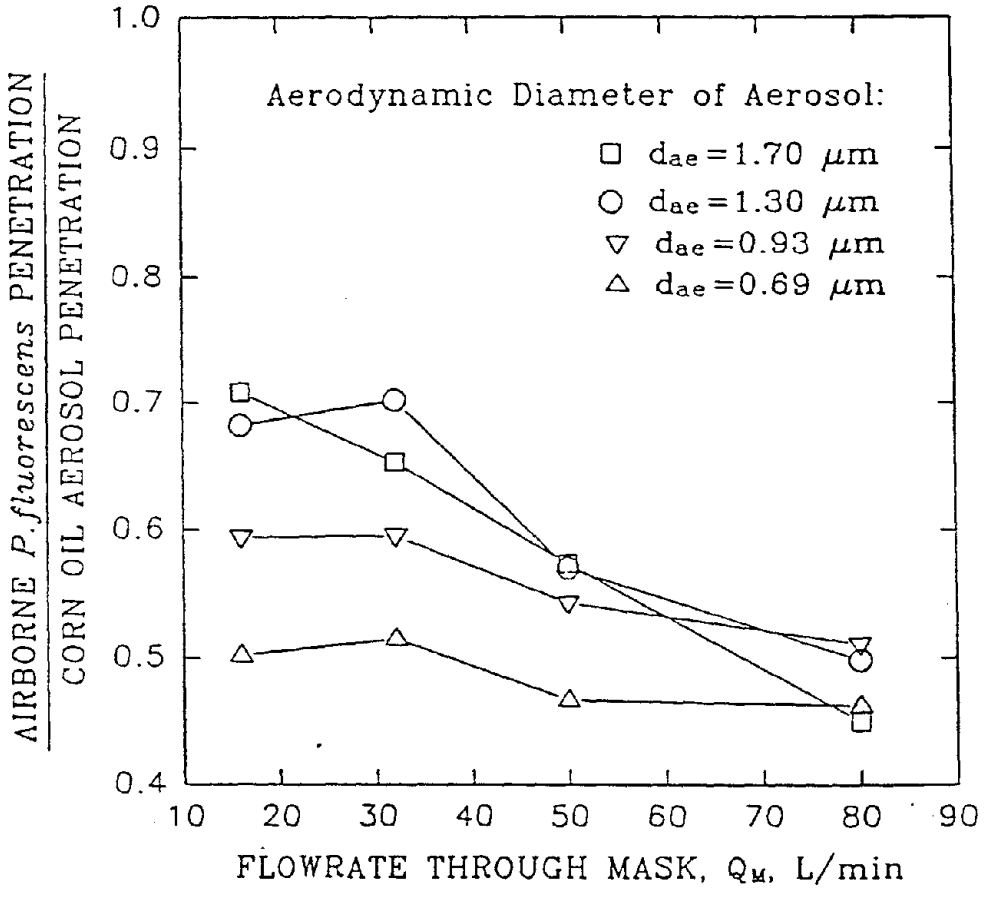


Figure 4. Aerosol penetration difference between *Pseudomonas fluorescens* (physically simulating TB bacteria) and corn oil as a function of flow rate and particle size.

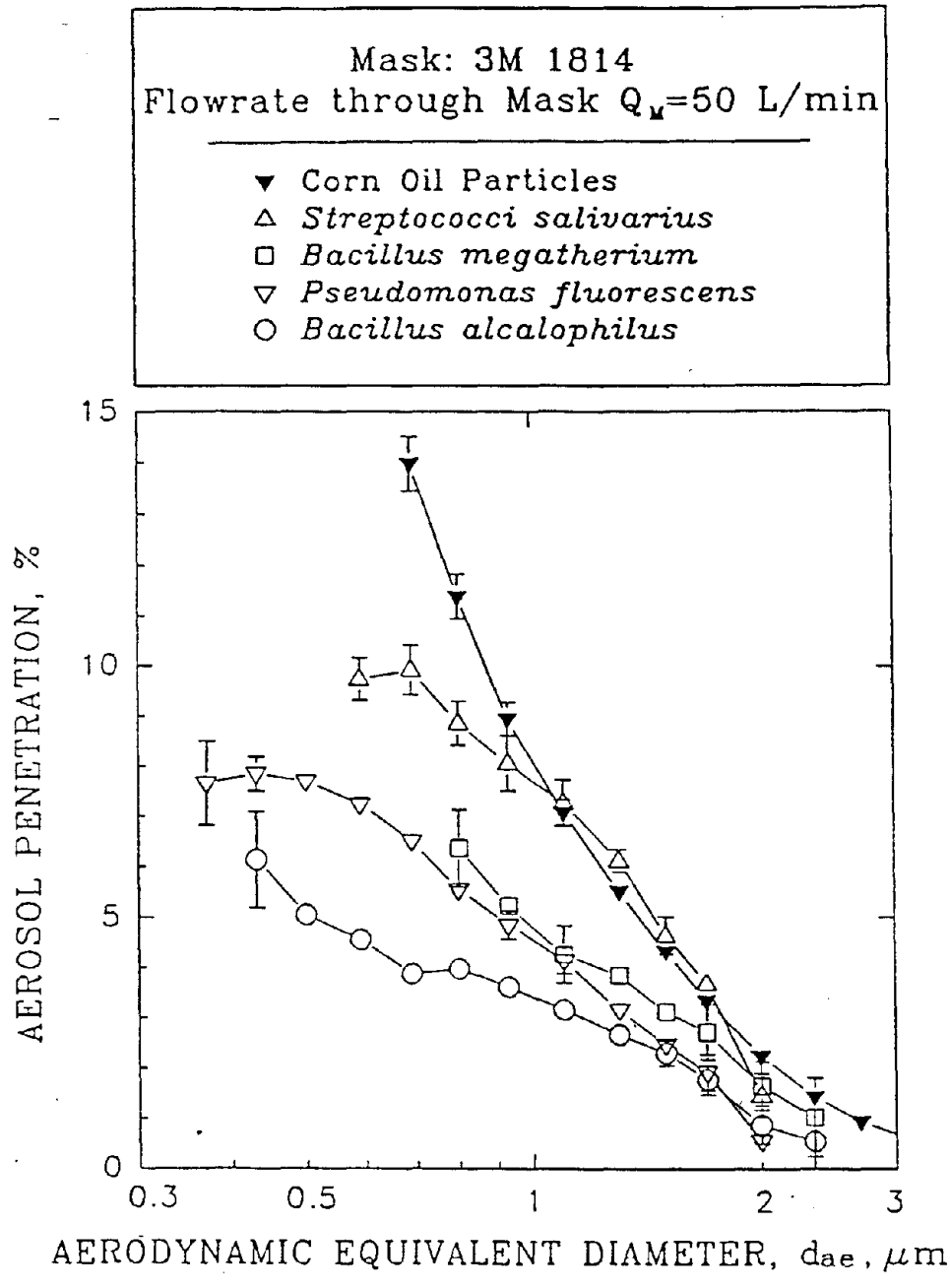


Figure 5. Aerosol penetration efficiencies for corn oil and four microorganisms of different size and shape.

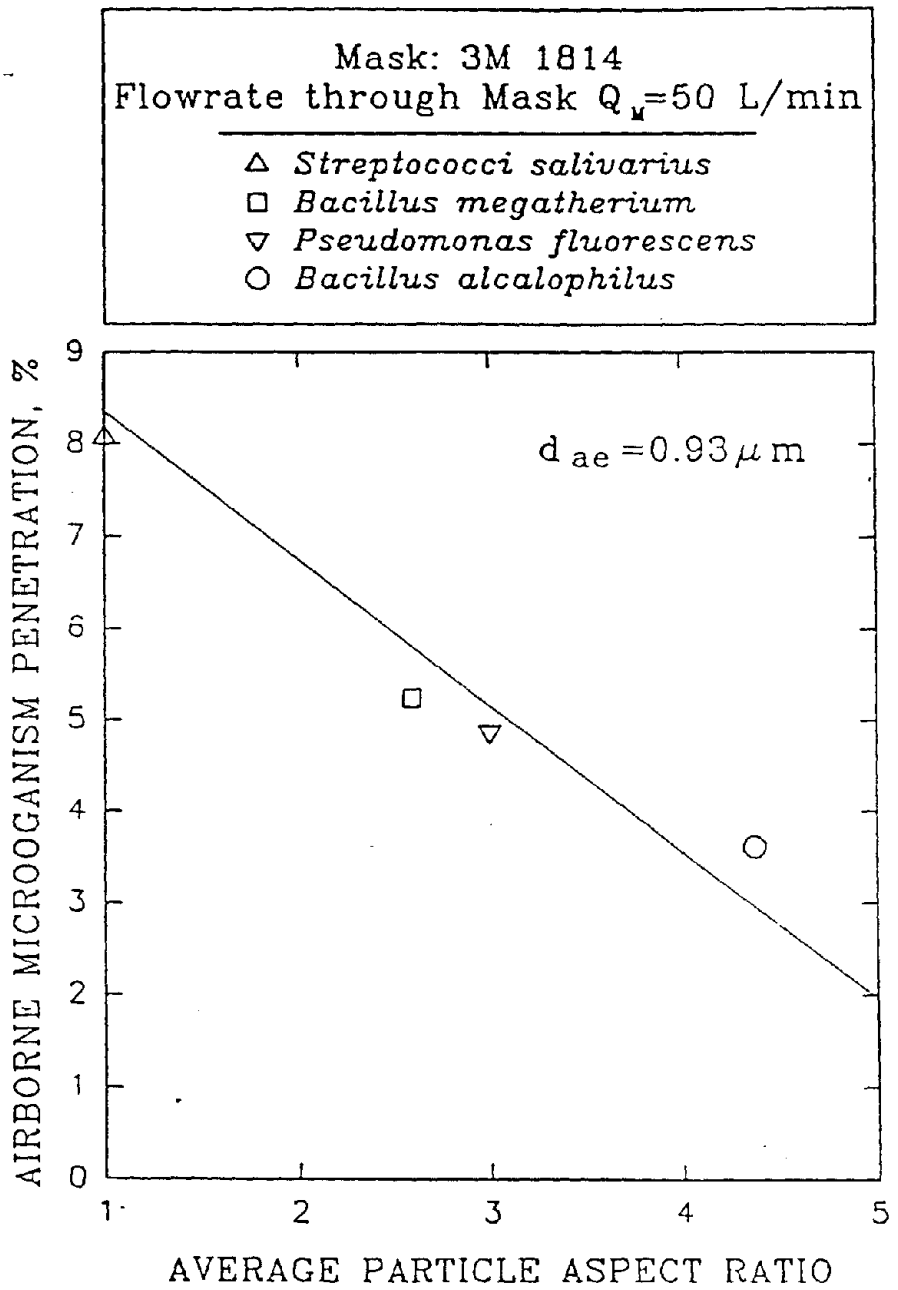


Figure 6. Reduction of bacterial filter penetration as a function of their aspect ratio .

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5. Report Date: 1995/06/29

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7. Author(s): Willeke, K.

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9. Performing Organization Name and Address: Department of Environmental Health, College of Medicine, University of Cincinnati, Cincinnati, Ohio

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14.

15. Supplementary Notes

16. Abstract (Limit: 200 words) Surgical masks and respirators currently in use or being considered for use in the health care industry were evaluated. Collection efficiencies with bacteria were compared to those with inert, nonliving test particles currently used to evaluate the performance of industrial masks and respirators. If there was an adequate face seal fit of the mask to the face of the wearer, the findings indicated that higher efficiency filters in health care masks worked better. When there was a large face seal leak, the higher performance mask may actually perform worse than a less efficient mask, as the higher pressure drop across the higher performance mask directs more air flow through the face seal leak. Spherical Streptococcus-salivarius bacteria were able to penetrate as efficiently as inert corn-oil test particles in the size range from 0.9 to 1.7 micrometers. Less penetration was noted with rod shaped bacteria. The ratio of the length to the diameter of the bacteria was an important factor. A filter 95% efficient against spherical test particles may be 97 to 97.5% effective against Mycobacterium-tuberculosis bacteria. A respirator with only about 90% efficiency against spherical test particles or microorganisms would be needed to meet the regulation requiring 95% efficiency against rod shaped bacteria.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms: NIOSH-Publication, NIOSH-Grant, Grant-Number-R01-OH-02948, End-Date-08-31-1995, Respirators, Personal-protective-equipment, Respiratory-protection, Equipment-design, Equipment-reliability, Infection-control, Microorganisms

c. COSATI Field/Group

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