

CONTENTS

REPORT

Abbreviations	ii
Highlights of the NIOSH Health Hazard Evaluation.....	iii
Summary	v
Introduction.....	1
Assessment.....	2
Results.....	8
Discussion	10
Conclusions.....	11

APPENDIX A

3M Model 8000, N95 Filtering Facepiece Respirators.....	12
---	----

APPENDIX B

NIOSH Standard Test Procedure No. TEB-APR-STP-0059.....	13
--	----

APPENDIX C

NIOSH Standard Test Procedure No. TEB-APR-STP-0003.....	25
--	----

APPENDIX D

NIOSH Standard Test Procedure No. TEB-ARP-STP-0007.....	34
--	----

APPENDIX E

Test Sample Respirators Prepared for Filter Efficiency and Airflow Resistance (Inhalation/Exhalation) Testing	45
--	----

APPENDIX F

40-Member NIOSH Bivariate Fit Test Panel for NIOSH Investigation of 3M Model 8000 Filtering Facepiece Respirator Fit Testing.....	46
---	----

ACKNOWLEDGMENTS

Acknowledgments and Availability of Report.....	47
---	----

ABBREVIATIONS

Cal/OSHA	California Occupational Safety and Health Administration, Division of Occupational Safety and Health
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CFM	Cubic feet per minute
CFR	Code of Federal Regulations
FFR	Filtering facepiece respirator
HETA	Hazard Evaluations and Technical Assistance
Lpm	liters per minute
mg/m ³	milligrams per cubic meter
NAICS	North American Industry Classification System
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
OSHA	Occupational Safety and Health Administration
PPT	Personal protective technology
SME	Subject matter expert
STP	Standard test procedure

HIGHLIGHTS OF THE NIOSH HEALTH HAZARD EVALUATION

What NIOSH Did

On December 23, 2009, the National Institute for Occupational Safety and Health (NIOSH) received a technical assistance request from the California Occupational Safety and Health Administration, Division of Occupational Safety and Health. The request reported a concern over difficulties fitting 3M Model 8000 respirators among employees exposed to 2009 H1N1 pandemic influenza at several facilities of a large healthcare organization. The organization had received the respirators in a distribution of product from the California Department of Public Health (CDPH) respirator stockpile.

- The performance of sample 3M Model 8000 filtering facepiece respirators (FFRs) received from the CDPH stockpile were checked to confirm their ability to meet the same requirements as needed for NIOSH approval. A series of evaluations and document reviews were performed by NIOSH subject matter experts.
- Performance tests were conducted to determine filter efficiency.
 - Airflow resistance performance tests were conducted to ensure the breathing resistance did not exceed the maximum pressure drop allowed for NIOSH approval.
 - Visual inspections were conducted with sample respirators for evidence that they were well-constructed of good materials and workmanship (e.g. placement, attachment, length, elasticity of headband straps).
 - Detailed document reviews were performed of NIOSH and 3M quality assurance documentation to ensure there weren't any issues or concerns of non-compliance with normal quality control practices or requirements of the 3M quality control plan during the manufacture of the respirators stockpiled by the CDPH.
- A literature search was conducted to review all peer-reviewed, published respirator research studies that specified the 3M Model 8000 respirator as a model whose fitting characteristics were assessed.
- Unpublished laboratory test results were reviewed to assess data on fit test trials following FFR decontamination procedures on FFR models of similar construction to the 3M model 8000 respirator.
- Twenty 3M Model 8000 N95 FFRs were tested to validate conformity with NIOSH certification procedures.
- Sample 3M Model 8000 FFRs for 2 sets of tests, were evaluated for their performance on a panel of 40 human test subjects representing a variety of facial features proportionately distributed across the NIOSH bivariate panel.

HIGHLIGHTS OF THE NIOSH HEALTH HAZARD EVALUATION (CONTINUED)

What NIOSH Found

- The performance tests and review of quality assurance records and inspections for quality of materials and workmanship revealed compliance with applicable approval requirements. The 3M Model 8000 respirators representatives of the CDPH stockpile:
 - Met the filter efficiency requirements for the approval of N95 FFRs.
 - Met the airflow resistance requirements for the approval of N95 FFRs.
 - Did not exhibit any issues or cause concerns of non-compliance with normal quality control practices or the requirements of the 3M quality control plan.
- No peer-reviewed published research studies were identified that specified the 3M Model 8000 respirator as one of the tested respirator models.
- In reviewed unpublished laboratory test results, subject matter experts found a pass rate of approximately 40% to 60% of test subjects to be within the expected performance levels for FFRs of similar construction to the 3M Model 8000 respirator.
- The sample respirators demonstrated fit test passing results on 22 and 25 of the 40 subjects in the two sets of trials.

NIOSH investigators assessed sample units of the 3M Model 8000 FFRs received from the CDPH stockpile in order to check for any non-compliance with the NIOSH approval requirements for filtration efficiency and airflow (breathing) resistance. The goal was to determine if the respirators were manufactured in accordance with the NIOSH-approved quality assurance plan and had appropriate construction and workmanship. The investigation also evaluated respirator performance when fit tested on a panel of human test subjects representing a variety of facial dimensions. The evaluation revealed that the performance tests, reviews of quality assurance records, and material and workmanship inspections were in compliance with applicable approval requirements. Additionally, sample respirators had fit test passing results on 22 and 25 of the 40 subjects in two trials. The NIOSH investigation determined that the fit test pass rate reported at the various facilities of a California healthcare organization did not result from any defect in the units' characteristics on which the product was certified.

The CDPH established a stockpile of respirators for use by healthcare personnel during an outbreak of pandemic influenza. The stockpile included an assortment of FFRs including approximately 32 million 3M Model 8000 N95. The CDPH's stockpile of respirators was made available for healthcare worker use during an outbreak of pandemic influenza in Fall, 2009. In addition to the CDPH's reserves, the CDC distributed a supplement of approximately 4 million 3M Model 8000 N95 FFRs to the CDPH from the federal government's Strategic National Stockpile, which is maintained and managed by CDC. Healthcare facilities within California that were experiencing shortages of respirators for the protection of healthcare personnel received respirators distributed from the CDPH stockpiled respirators, including this 3M model.

On December 23, 2009, NIOSH received a request for assistance from Cal/OSHA. Cal/OSHA was concerned that a large healthcare organization was unable to successfully fit test their healthcare workers with the 3M Model 8000 N95 FFR received from the California stockpile. The healthcare organization conducted the initial set of fit tests using the Bitrex® qualitative fit test protocol, and none of the approximately 20 workers who were fit tested obtained an acceptable fit (pass rate of 0%). A second group of 20 workers were reported to have obtained a fit test pass rate of 40% (8 of 20) with fit tests conducted by 3M representatives using the TSI PortaCount® with N95 Companion® quantitative fit test protocol. The California experience with these devices raised questions about whether the subject units had a defect of some type whereby they may have been non-conforming to the NIOSH approval. SMEs from the NIOSH NPPTL conducted the technical assistance investigation.

The purpose of the NIOSH investigation was to determine whether the fit test pass rate reported at the various facilities of a California healthcare organization resulted from any defect in the units' characteristics on which the product was certified (e.g., filter efficiency at the N95 criteria, workmanship, or quality of manufacture) as believed by Cal/OSHA and CDPH. To address the concerns, NIOSH requested and received samples from the remaining stockpiled 3M Model 8000 respirators from CDPH for inspection, testing and evaluation. The activities were divided into five parts: (1) assessment of compliance with requirements for NIOSH respirator certification, (2) assessment of conformance with quality assurance provisions incorporated into the NIOSH

approval, (3) respirator research review, and (4) fit test trials using the CDPH-supplied 3M 8000 respirators.

This investigation was limited to conformity assessment of the respirators to the NIOSH approval requirements and did not include efforts to evaluate the California healthcare organization's fit testing programs, or to conduct additional fit testing on the actual healthcare workers who failed the California fit tests. The investigation revealed that the 3M Model 8000 respirators complied with all applicable approval requirements, which do not include assessment of fit characteristics. The respirators were additionally tested for their ability to fit test subjects representative of the NIOSH Bivariate fit test panel. The sample respirators demonstrated fit test passing results on 22 and 25 of the 40 subjects in the two sets of trials.

The investigation found no issues or concerns of non-compliance with normal quality control practices or the requirements of the 3M quality control plan during the manufacturing of the respirators in the CDPH stockpile. As a result of these findings, no further actions will be taken.

Keywords: NAICS 622110 (General Medical and Surgical Hospitals), Healthcare, Cal/OSHA, filtering facepiece respirator, filtration efficiency, breathing resistance, respirator performance.

Cal/OSHA was notified in November 2009, by a large healthcare organization of difficulties in fitting the distributed 3M Model 8000 respirators to workers at several of their facilities. Based upon recent fit testing at hospitals in California, 3M Model 8000 N95 FFRs from the CDPH Stockpile achieved fit test pass rates that were deemed to be unacceptably low for use by the healthcare workers. This experience caused CDPH and Cal/OSHA to believe the model 8000 respirators distributed from the California stockpile to be unusable due to defects in those units. The Cal/OSHA Division of Occupational Safety and Health contacted NIOSH on December 23, 2009 to request NIOSH's assistance. Cal/OSHA reported to NIOSH that the healthcare organization conducted the initial set of fit tests using the Bitrex® qualitative fit test protocol and none of the approximately 20 workers who were fit tested obtained an acceptable fit (pass rate of 0%). A second group of 20 workers were reported to have obtained a fit test pass rate of 40% (8 of 20) with fit tests conducted by 3M representatives using the TSI PortaCount® with N95 Companion® quantitative fit test protocol. Cal/OSHA also notified its stakeholders of this issue on December 23, 2009. The California experience with these devices raised questions about whether the subject units had a defect of some type whereby they may have been non-conforming to the NIOSH approval. A widespread quality problem would have immediate implications for other respirator purchasers who have stockpiled this particular model of respirator. The NIOSH NPPTL initiated a technical assistance investigation of the stockpiled 3M Model 8000 N95s under the health hazard evaluation program based on the Cal/OSHA request for assistance.

Background

The 3M Model 8000 N95 FFR is approved by NIOSH and, as a condition of approval, must be used in the context of a comprehensive respiratory protection program. When respirators are used in the workplace regulated by OSHA, a comprehensive respiratory protection program must be in place as required by OSHA's Respiratory Protection standard 29 CFR 1910.134. This investigation did not include efforts to evaluate the California healthcare organization's fit testing programs, or to conduct additional fit testing on the actual healthcare workers who failed the California fit tests. The purpose of this investigation was to determine whether the fit test pass rate reported at the various facilities of a California healthcare organization resulted from any defect in the units' characteristics on which the product was certified (e.g., filter efficiency at the N95 criteria, workmanship, or quality of manufacture). To address these concerns, NIOSH requested and received samples from the remaining stockpiled 3M Model 8000 respirators from CDPH for inspection, testing, and evaluation.

The sample respirators that NIOSH received for this investigation were labeled as being manufactured during either of two production

INTRODUCTION (CONTINUED)

lots: lot 17040-05 or lot 17040-06. The investigation was conducted to assess the sample units of the 3M Model 8000 FFRs received from the CDPH stockpile for any non-compliance with the NIOSH approval requirements for performance of filtration efficiency and airflow (breathing) resistance. The goal was to determine if the respirators were manufactured in accordance with the NIOSH-approved quality assurance plan, and that the respirators showed no evidence of poor workmanship. The investigation also evaluated respirator performance when fit tested on a panel of human test subjects representing a variety of facial dimensions. The activities were divided into five parts: (1) assessment of compliance with requirements for NIOSH respirator certification, (2) assessment of conformance with quality assurance provisions incorporated into the NIOSH approval, (3) respirator research review, and (4) fit test trials using the CDPH-Supplied 3M 8000 respirators.

Appendix A provides photographs showing the 3M Model 8000 FFR (obtained from advertising sources). Figure A1 shows the 3M Model 8000 respirator, with the NIOSH abbreviated approval label. Figure A2 includes the normal 3M packaging.

ASSESSMENT

Assessment of Compliance with Requirements for NIOSH Respirator Certification

Approval requirements with the potential to affect the respirators' ability to fit properly were identified as:

- Filter efficiency and airflow resistance tests, and
- Visual assessment for quality of materials and workmanship evidenced in the sample units.

Filter efficiency and airflow resistance tests

NIOSH conducted performance tests used in the respirator certification program on sample respirators from both manufacturing production lots (lot 17040-05 and lot 17040-06). Ten respirators from each lot received from the CDPH stockpile were used for the filter efficiency testing. The filter efficiency tests were conducted on the 20 respirators in accordance with the *National Institute for Occupational Safety and Health (NIOSH) Standard Test Procedure No. TEB-APR-STP-0059, Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators* (Appendix B). This test procedure ensures that the level of protection of N95 series filters used on non-powered respirators meet the minimum certification standards set forth in 42 CFR part 84,

Subpart G, Section 84.181. The airflow resistance tests on the sample respirators were conducted in accordance with the *National Institute for Occupational Safety and Health (NIOSH) Standard Test Procedure No. TEB-APR-STP-0003, Determination of Exhalation Resistance Test, Air-Purifying Respirators (Appendix C)*, and *National Institute for Occupational Safety and Health (NIOSH) Standard Test Procedure No. TEB-APR-STP-0007, Determination of Inhalation Resistance Test, Air-Purifying Respirators (Appendix D)* to ensure the FFRs met the minimum certification standards for airflow resistance requirements set forth in 42 CFR part 84, Subpart G, Section 84.180 for filters used on non-powered respirators.

The FFRs were pre-conditioned at 85 +/- 5% relative humidity and 38 +/-2.5°C for 25 +/- 1 hours. Each FFR was mounted and sealed on holders to prevent leakage around the filter holder and tested at a challenge flow rate of 85 +/- 4 Lpm using a TSI Model 8130 Automated Filter Tester (TSI Incorporated, Shoreview, Minnesota). The filters were challenged with a sodium chloride aerosol at 25 +/- 5 °C and a relative humidity of 30 +/- 10% that had been neutralized to the Boltzmann equilibrium state. The challenge aerosol had a particle size distribution of a count median diameter of 0.075 +/- 0.020 micrometer and a geometric standard deviation not exceeding 1.86. Each FFR was challenged with an aerosol concentration not exceeding 200 mg/m³ in accordance with the test procedure. Tests were conducted, and the results recorded in accordance with the appropriate STPs. Appendix E contains photographs of the sample respirators as they were prepared for the filter efficiency and airflow resistance performance tests. Figures E1 and E2 show the respirators with the headband straps removed to allow mounting and sealing on the filter holder to prevent airflow leakage around the edge of the filter as mounted for testing. Figures E3 and E4 show sample respirators after mounting and sealing with beeswax to the flat Plexiglas plate used for most FFRs in this filter testing.

Visual assessment for quality of materials and workmanship

The sample respirators were also inspected for visual evidence of good materials and workmanship. Similar visual assessments have been part of the normal certification evaluation activities to make sure that the units submitted for approval evaluation are well-constructed (e.g. placement, attachment, length, and elasticity of headband straps).

Assessment of Conformance with Quality Assurance Provisions Incorporated into the NIOSH Approval

NIOSH evaluates proposed quality control processes and procedures to monitor the manufacturing of certified respirators in order to

assure their continued quality during documentation review of approval applications. NIOSH also conducts post-certification auditing of manufacturing sites and off-the-shelf certified products for compliance to the quality assurance related requirements of the products' approval. For this investigation, NIOSH reviewed the NIOSH-accepted quality control documentation for the certification of the 3M Model 8000 respirator and the post-certification auditing of the manufacturing site. NIOSH also reviewed the 3M quality control records from the monitoring of both manufacturing production lots, lots 17040-05 and 17040-06, in which the sample respirators were produced.

Quality assurance requirements for the 3M Model 8000 respirator

The 3M Model 8000 respirator is manufactured in a two step process. The cup part is molded in the first step. The straps and noseclip are affixed to the molded cup in the second, finishing step. The 3M Quality Control plan which is incorporated as part of the NIOSH-certification documentation includes two types of testing and procedures to be conducted for the manufacturing process. In-process testing of sodium chloride initial filter penetration and breathing resistance is done on samples of each manufacturing lot of the molded cup before they enter into the finishing step. Sample finished products are checked for sodium chloride initial filter penetration at the conclusion of the finishing step. An additional sample for each manufacturing production lot of the molded cup is tested to 200 milligram loading of the sodium chloride aerosol, as part of the release testing in accordance with the quality control plan.

Review of NIOSH quality assurance documentation

The two manufacturing production lots represented by the sample 3M Model 8000 FFRs received from the CDPH stockpile, lot 17040-05 and lot 17040-06, were identified as manufactured at the 3M Aberdeen, South Dakota facility. A review was conducted of the NIOSH documentation of recent manufacturing site quality assurance audits of that facility. A manufacturing site audit was completed on November 22, 2005, and another was conducted on October 30, 2008.

Review of 3M quality assurance documentation

Molded cups used at the finishing step of a single production lot can include cups molded in multiple lots from the molding step.

Therefore, the assembled respirators identified as produced within a single finishing step production lot can include molded cups from either the same day or several days of the molding step production. Molded cups from lots 17040-05 and 17040-06 were used in three finishing step (final) lots. The 3M quality control documentation from the in-process and final release testing of all molding step and finishing step lots that would be contained in manufacturing production lots 17040-05 and 17040-06 were obtained from 3M. NIOSH reviewed the 3M quality records as part of the investigation's quality assurance assessment.

Respirator Research Review

NIOSH conducts PPT research to advance the state of science and close knowledge gaps concerning personal protective equipment and its use. The NIOSH research is conducted in support of, and as part of the NIOSH PPT Program.

Literature review of published research studies

NIOSH researchers conducted a literature search and review of peer-reviewed published respirator research studies that assessed respirator fitting characteristics. The NIOSH-conducted literature review of available research reports did not identify any peer-reviewed published research studies that specified the 3M Model 8000 respirator as one of the tested respirator models in a reported study.

Review of unpublished NIOSH data

The NIOSH researchers were aware of unpublished data collected during a NIOSH research project evaluating the ability of FFRs to be decontaminated after exposure to bioaerosols. The 3M Model 8000 respirator was one of the six FFR models included in the NIOSH study because it was one of the FFR models in the CDC Strategic National Stockpile. The determination of the fitting performance of the six FFR models used was not a goal of the study. However, the impact of subjecting the various respirator models to the candidate decontamination procedures on the FFR fitting characteristics was unknown. The NIOSH researchers anticipated that the study might be expanded to include fit assessments on human test subjects before and after potential decontamination procedures. They conducted fit test trials using a number of human test subjects with samples of the respirator model prior to their being subjected to the decontamination techniques. This process was done for the various models so baseline performance data would be available to evaluate the ability of FFRs to retain their fitting characteristics after undergoing decontamination procedures.

For the decontamination study, 18 human test subjects who typically are among the available test subjects for NIOSH respirator test procedures were available for fit test trials, and were fit tested on the 3M Model 8000 FFRs before the respirators were subjected to the biological decontamination methods. The 18 test subjects did not represent the full range of facial dimensions reflected in either the Los Alamos National Laboratory panel developed for NIOSH in the 1970's or the recently-developed NIOSH Bivariate panel. The NIOSH Bivariate panel, based on a 2003 NIOSH-conducted anthropometric survey of 3,997 US workers, represents the diverse range of facial dimensions of respirator wearers in the US workforce. Fit test trials using the TSI PortaCount® with N95 Companion® were conducted on the 18 available test subjects.

Fit Test Trials with the CDPH-Supplied 3M 8000 Respirators

The NIOSH respirator certification program is supported through the development and promulgation of standards and regulations. NIOSH conducts applied research and develops test procedures in support of the activities to develop criteria for evaluation of proposed performance parameters for PPT. NIOSH conducted two sets of performance tests to assess the fitting capability performance of the sample respirators from the CDPH stockpile. One set of tests were conducted using a 40-member NIOSH Bivariate panel and representative samples for each of the two manufacturing production lots.

Background for NIOSH fit test trials

The two separate lots of 3M Model 8000 FFRs (17040-05 and 17040-06) were quantitatively fit tested on a panel of 40 human test subjects at the NIOSH test facilities, Pittsburgh, Pennsylvania. The human test subjects were experienced respirator wearers from within the group of persons normally used for test panel evaluations of respirator fit in the NIOSH respirator certification program. Participating human test subjects for these fit test trials were selected based on their facial dimensions meeting the proportional distribution of facial sizes of the NIOSH Bivariate panel, and their availability for completing the six fit test trials being conducted for this investigation (3 trials using a respirator from each production lot was performed for both production lots representative of the CDPH stockpile of respirators). The facial dimensions of the 40 human subjects used for this test program were proportionally distributed into the NIOSH Bivariate panel (see Appendix F).

Conduct of the NIOSH fit test trials

The fit test trials were conducted by NIOSH personnel using the TSI PortaCount® with N95 Companion®. The OSHA-accepted fit test protocol and exercise regimen were followed. As with the OSHA-accepted fit test protocol, an overall fit factor equal to or greater than 100 was used for the pass/fail fit factor for all fit test trials. TSI, Inc. FitPlus version 3 Fit Test software was used to administer all fit test trials. This software provides a fully automated fit test process that includes and follows the OSHA Fit Test Protocol exercise routines and sequence. After entering the start command, the first exercise description appears as a graphic progress bar. As each exercise completes, the FitPlus version 3 Fit Test software provides a warning to indicate that it is time to begin the next exercise and continues this process until all exercises are completed. Additionally, test subjects were instructed to take only one breath at each exercise hold point, where applicable (head side-to-side, head up-and-down, etc.) in a further attempt to minimize variability in performing the exercise regimen among the trials. Each respirator was probed prior to the start of testing, with the PortaCount sample line connected to the mask probe before the test subject donned the respirator. The PortaCount sampling pendant was installed after the respirator was donned. The pendant was used to hold the sample line in place on the test subject's chest, thereby minimizing the sampling line pulling on the FFR during the fit test exercises.

Each fit test trial required a donning conducted in strict accordance with 3M's instructions and the test subject's independent assessment that the user's seal check successfully represented an acceptable fit had been attained. Prior to testing, each test subject reviewed the 3M user instructions to familiarize themselves with the selection, donning, and fitting procedures for the 3M Model 8000 respirator. Each test subject performed an assisted donning of the pre-probed respirator in accordance with the manufacturer's user instructions and was permitted to make the appropriate adjustments until satisfied they were wearing the respirator in accordance with the instructions. Test administrators monitored the donnings to assure that the FFR was properly donned by the test subject and provided additional training as necessary to assure conformance to the user instructions during respirator donning and adjustment. Following a user seal check and documentation of the results, each test subject wore the respirator for at least 5 minutes before beginning the test. After completion of each fit test trial, the respirator was doffed and the metal noseclip was reshaped to its original configuration by the test operator prior to the respirator being re-donned for the next fit test trial. This was done to assure that the same fitting procedures were required to be performed every time the respirator was donned in a fit test trial.

ASSESSMENT (CONTINUED)

Each of the 40 test subjects performed a total of six fit test trials consisting of three donnings of a respirator for each production lot (17040-05 and 17040-06) received from the CDPH stockpile. One respirator was used for the set of three trials for each production lot. For this investigation, a test subject receiving at least one acceptable fit test result, i.e., a fit factor of 100 or greater, from the three trials per respirator was defined as having passed the fit test with that respirator.

RESULTS

No issues of non-conformance to the approval requirements for this respirator model were identified in any of the assessments performed under this investigation. No acceptable minimum pass rate was established for fit test trials of the 3M Model 8000 respirators. The sample respirators demonstrated fit test passing results on 22 (55%) and 25 (62.5%) of the 40 subjects in the two sets of trials.

Summary of Results for NIOSH Activities Assessing Compliance with Certification Requirements

No issues of non-compliance were identified in the assessment of approved performance, materials, and workmanship. All NIOSH certification requirements assessed by the performance testing and visual inspections conducted by NIOSH personnel on the 20 sample respirators were judged to be met. Based on these results, the respirators produced in lot 17040-05 and lot 17040-06 were determined to have been manufactured in conformance with the terms of the NIOSH certification of the 3M Model 8000 FFR.

Summary of Results for Activities Assessing Compliance with Quality Assurance Requirements

Only three minor findings, identified as a consequence of the October 2008 audit, were noted from auditing of the Aberdeen manufacturing facility. The minor findings from this audit have since been resolved. The detailed review of NIOSH and 3M quality assurance documentation for the manufacture of the 3M Model 8000 FFR did not reveal any issues or concerns of non-compliance with normal quality control practices or the requirements of the 3M quality control plan incorporated as a condition of NIOSH certification.

Summary of Results for NIOSH Activities Assessing Literature Review of Research Studies

The NIOSH researchers reviewed the unpublished data for fit test trials performed during a NIOSH project investigating FFRs subjected to potential decontamination procedures. Twelve of 18 test subjects were able to achieve acceptable results of a protection factor of 100 or more using the 3M Model 8000 respirators. The facial dimensions of most of these test subjects placed them in the middle of the NIOSH Bivariate panel, and, therefore, their face size distribution was not representative of the U.S. population. Although the results do not represent actual workplace conditions, they do serve as an indicator of performance likely representing a scenario that can be used as a guide for potential fit test performance of this respirator model. No acceptable minimum pass rate has been established for fit test trials of FFRs. The data from fit test trials of the various FFR models in the NIOSH decontamination study included results of higher pass rates for some models and lower pass rates for others. As a result of this review, the experience and professional judgment of NIOSH research SMEs found a pass rate of approximately 40% to 60% of test subjects to be within the expected performance levels for FFRs of similar construction to the 3M Model 8000 respirator for comparison with the reported California experience and the fit test trials conducted by NIOSH in this investigation. Unpublished data within the NIOSH project database were consistent with these expectations.

Summary of Results for Activities Assessing Fitting Characteristics

No acceptable minimum pass rate was established for the fit test trials of the 3M Model 8000 respirators. Using the investigation criteria for conducting the fit test trials and determining whether the fit test had been passed by a test subject, the following fit test pass rates were achieved by the 40 panel members:

22 test subjects of the 40-member panel (55%) achieved passing results on the NIOSH -conducted fit tests using the OSHA-accepted TSI PortaCount® with N95 Companion® fit test protocol and respirators from lot 17040-05.

25 test subjects of the 40-member panel (62.5%) achieved passing results on the NIOSH -conducted fit tests using the OSHA-accepted TSI PortaCount® with N95 Companion® fit test protocol and respirators from lot 17040-06.

NIOSH technical assistance investigation of the 3M Model 8000 N95 FFR was initiated by the NIOSH NPPTL based on the Cal/OSHA notification of a suspected product defect and request for assistance. The investigation included NIOSH evaluation, inspection, and testing of fit-related parameters of representative samples of the California-stockpiled respirators of this model. The filter efficiency and airflow (breathing) resistances of the tested respirators met the performance requirements for NIOSH FFR approval. The NIOSH-conducted investigation did not reveal any issues where the representative respirators exhibited non-compliance with the approval requirements. Fit test trials resulted in 40 test subjects with facial dimension sizes and distribution in accordance with the NIOSH bivariate panel achieving fit test passing results for 22 (55%) of 40 subjects in one set of trials and 25 (62.5%) of 40 subjects in the second set of trials. No acceptable minimum pass rate has been established for fit test trials of FFRs.

The reported pass rate of 0% for the Bitrex® qualitative fit tests conducted by the healthcare organization for the initial set of approximately 20 workers, as well as the pass rate of 40% (8 of 20) for a second group of 20 workers who were fit tested by 3M representatives using the TSI PortaCount® with N95 Companion® quantitative fit test protocol, are neither inconsistent with each other, nor with the results of the fit test trials conducted under this investigation. The consequences of momentary or short-term breaches in the seal between the respirator's sealing surface and the test subject's face can be significantly different between a qualitative fit test and a quantitative fit test. The pass/fail criteria for a qualitative fit test protocol relies on the test subject's sensory detection of the test agent at any time during the conduct of the test, while the determination for quantitative fit test protocols is based on the overall protection level determined by averaging the protection levels measured for the individual exercises used in the protocol. The Bitrex® qualitative fit test protocol depends on the worker's detection of the bitter taste of the Bitrex at the sensitivity level to determine a protection level less than the acceptable minimum. A momentary breach in the seal between the respirator's sealing surface and the test subject's face during any portion of the protocol's exercise regimen may be detected, thereby causing failure of the fit test. A similar momentary breach in the seal during a quantitative fit test may be evidenced in a much lower protection level reading for the time period that the breach exists, but not reduce the overall protection factor enough to result in a failure of the fit test. How many of the workers who failed the Bitrex® fit test protocol due to short-term breaches in the respirator-to-user seal would have passed a quantitative fit test for that same donning is unknown. However, the respirators' performances were consistent with NIOSH experience and professional judgment of expected performance based on respirator research, certification, and policy and standards development activities.

DISCUSSION (CONTINUED)

The 3M Model 8000 FFR is designed as a single-sized design. The California experience underscores the longstanding OSHA and NIOSH positions on the importance of fit testing to assure that the particular make and model of respirator selected actually fits each individual worker who will use it. No respirator can be guaranteed to fit 100% of users, and OSHA regulations require an assortment of models and sizes of respirators be available for selection at the time of fit testing. Due to anthropometric differences in the American workforce, a variety of respirators may have to be tested to achieve a good fit for an individual worker. The experience also highlights the importance of and need to assure that multiple makes/models/sizes of respirators are acquired to provide users with a variety of respirator fit options.

The 40% fit test pass rate reported by Cal/OSHA for the 3M Model 8000 FFR as part of the request for NIOSH assistance does not indicate that the units of this model are defective. No acceptable minimum pass rate has been established for workplace fit testing of a respirator model. Numerous factors aside from defects to the respirator units can affect the fit test outcome, such as worker facial dimensions, the ability and ease of conforming the respirator seal (including the noseclip) to the worker's face, the quality of the administration of the fit test protocol, type and level of training provided to intended users, the experience levels and expectations of the workers being fit tested, etc. The fit test trials conducted under this NIOSH investigation were performed on a representative panel of 40 experienced test subjects with facial size distributions that approximate the facial sizes and distributions representative of respirator users in the U.S. workforce.

CONCLUSIONS

The purpose of this investigation was to determine if there was a widespread quality problem that caused the subject units to have a defect of some type whereby they may be non-conforming to the NIOSH approval. Therefore, this investigation did not include efforts to evaluate the California healthcare organization's fit testing programs, or to conduct additional fit testing on the actual healthcare workers who failed the California fit tests. The facial dimensions of the approximately 40 workers who participated in the fit testing at the California facilities and their distribution within the respirator user population is undetermined. At this time there is no evidence of a defect in the respirators or any indication that the respirators will not achieve the expected level of protection when used in accordance with the respirator standard (e.g., successful fit test, training, etc.).

APPENDIX B, C, D:

Appendix B: NIOSH Standard Test Procedure No. TEB-APR-STP-0059 is on the web at:

<http://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059.pdf>

Appendix C: NIOSH Standard Test Procedure No. TEB-APR-STP-0003 is on the web at:

<http://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-APR-0003.pdf>

Appendix D: NIOSH Standard Test Procedure No. TEB-APR-STP-0007 is on the web at:

<http://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0007.pdf>

