3M Occupational Health and
Environmental Safety Division

3M Center
St. Paul, MN 55144-1000
612 733 1110

94-372

3M

October 4, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop 34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Dear Sir/Madam:

On July 20, the Minnesota Mining and Manufacturing Company submitted comments (#94-289) to the National Institute for Occupational Safety and Health (NIOSH) docket on the agency's proposed revisions to its respirator certification standard. The proposed rule, which would replace the existing rules found at 30 CFR 11 and recodify them at 42 CFR 84, was published in the May 24, 1994 *Federal Register*.

The 3M comments favored revision of the existing respirator certification standard. The comments were substantial and were supported by extensive technical knowledge, experience and data.

Subsequent to the close of the comment period on July 22, NIOSH Senior Science Advisor Nelson Leidel submitted comments (#94-365) to the record. These comments were deemed significant by the agency and were admitted to the record, despite missing the deadline.

For the five year period from September 1987 to October 1992, Leidel was the 42 CFR 84 program manager within the Division of Safety Research. He presented a revised certification rule to the agency in September 1992 (included as a 748 page attachment to his comments), but significant objections to the proposal were raised and it was rejected by a panel of outside peer reviewers. Shortly after this negative assessment, Leidel was removed from his position as program manager at NIOSH.

Leidel's comments were highly critical of the judgment and impartiality of agency officials, and included negative references to a number of 3M respirators and the certifications these products had received from the agency under the current rule. The comments also made specific recommendations to counter what Leidel identified as problems with the proposed rule and with the existing certification program run by NIOSH's Division of Safety Research (DSR).

In his comments, Leidel specifically recommended that:

- NIOSH should create an independent outside panel to investigate all NIOSH certifications issued for particulate-filtering respirators;
- NIOSH should void the existing certification for the 3M 9970 HEPA mask respirator;
- NIOSH should withdraw the May 1994 NPRM; and
- NIOSH should withdraw from issuing product certifications unless it is willing to implement "FDA-style" testing and enforcement.

Leidel's comments also recommend that NIOSH investigate all alleged ex parte communications that took place prior to publication of the NPRM, and reject the modular approach it had adopted to facilitate the rulemaking. Leidel cites a "clear pattern of questionable conduct on the part of DSR personnel with regard to the granting of hundreds of Federal approval certifications for particulate-filtering respirators certified under Subpart K."

3M strongly disagrees with the recommendations and statements made in Leidel's comments to the 42 CFR 84 docket. In particular, we object to the portion of his comments that disparage the model number 9970 and 2040 3M respirators. We are submitting these additional comments of our own as a response and rebuttal to Leidel's allegations concerning the quality of, and certifications issued to, 3M products, and request that, in the interest of fairness, they also be included in the docket.

I. Deficiencies in the Testing Protocol

In the context of his call for assembly of an independent panel of outside experts to review all current NIOSH certifications for dust/fume/mist particulate filter respirators issued under 30 CFR 11, Leidel offers several specific criticisms of the approval process as conducted at DSR. He makes frequent reference in his comments to the so called "hidden hazards and deficiencies" in NIOSH-approved respirators, citing a "clear and consistent pattern of DSR personnel failing to warn respirator users and purchasers"

about these dangers. These allegations are based on what he claims are deficiencies in the NIOSH certification testing protocol.

In particular, Leidel cites two alleged deficiencies that he claims resulted in certification of 3M respirators that otherwise would not have received NIOSH approval. Leidel claims that DSR personnel granted 3M a "one-subject waiver" when performing fit testing in the laboratory. He also alleges that DSR personnel ran corn oil fit tests based on improper filter penetration percentages. Because of these alleged deficiencies, therefore, Leidel asserts that the 3M 9970 should be decertified

a. One subject waiver

The first of the "major procedural errors" that Leidel cites is his allegation that 3M was granted an exemption to the fit testing requirements of 30 CFR 11 when the 9970 respirator was certified in 1987 (See Leidel Appendix A, p. 46). In his discussion of DSR's facepiece testing, as required under 30 CFR 11.162-3, Leidel cites language in the 9970's certification records that includes a statement attributed to DSR's Nancy Bollinger (p. 48). The quoted Bollinger language indicates that, when subjected to the facepiece test, "One test subject will be allowed to detect the odor of isoamyl acetate." Leidel indicates that he was unable to obtain a copy of the original memorandum laying out this NIOSH policy. A copy of the 1982 NIOSH Fit Test Method permitting one test subject to detect an odor is included as 3M Attachment 1.

Based on his inability to locate this memorandum, Leidel asserts that "any alleged justification for this one-subject waiver is unknown at this time" (p. 48). Leidel concedes that "it is unknown if the waiver was ever approved by DSR management or NIOSH management" (p.49). He goes on to argue that NIOSH created this "one-subject waiver" without undergoing the normal notice and comment rulemaking process and thereby created "an unauthorized, improper, and invalid reduction in respirator-user protection by NIOSH DSR personnel" (p. 49).

Because the eighth subject tested under 30 CFR 11.162-3 failed the faceseal leakage test but still was granted certification, this improper "one-subject waiver," he argues, was then used by NIOSH to grant the 3M 9970 an invalid certification.

On the contrary, 3M has never been granted an "exemption" from any certification requirement. All respirator manufacturers, including 3M, have had to comply with this same requirement since NIOSH began certifying

respirators in 1972. Attachment 1 is a 1982 NIOSH Fit Test method which clearly states that "A maximum of one wearer will be allowed to detect the odor of isoamyl acetate" during certification fit testing.

Surprisingly, this requirement is consistent with Leidel's own 1992 proposal to revise 30 CFR 11. Leidel quotes language from that draft document stating that "NIOSH does not intend that a certified respirator must be capable of providing an APF level fit to every potential user. Instead each certified respirator model must be able to provide APF-level protection to a large proportion (e.g., 90%) of facial sizes and shapes" (Leidel, p. 38).

Requiring 9 out of the 10 test subjects to pass the current 30 CFR 11 requirement certainly appears consistent with the "large proportion (e.g., 90%)" requirement that he proposed in 1992. Nonetheless, Leidel now argues that permitting one subject out of ten to detect isoamyl acetate in a faceseal leakage test is an improper, unauthorized test methodology and renders the existing 3M 9970 certification to 30 CFR 11 invalid.

It is interesting to note that, since the original certification, 3M has made design changes to the 9970 respirator three times, which required NIOSH to retest the fit of the respirator according to the 30 CFR 11 certification requirements. In each of these retests, ten of ten test subjects passed the test. Documentation of the successful completion of this testing is included as 3M Attachment 2. In his comments, Leidel chose to ignore the continuing, consistently positive results that 3M achieved in this subsequent testing.

b. Improper Fit Testing

Mr. Leidel contends that the second "major procedural error" invalidating the 3M 9970's certification was the maximum faceseal leakage limit set by NIOSH when it performed a corn oil quantitative fit test. This test is designed to test the leakage of a respirator's faceseal and requires a respirator to meet a specified fit factor to obtain NIOSH certification. Each fit factor can be translated into a specific level of maximum acceptable faceseal leakage. NIOSH used a minimum fit factor of 10, which is equivalent to 10% maximum faceseal leakage as the test limit during these tests; Mr. Leidel contends the minimum fit factor should have been 100, which is a maximum faceseal leakage limit of 1%.

The corn oil quantitative fit test is not an explicit requirement in 30 CFR 11. Instead, it is run as an additional test under what is commonly referred to as the "General Duty" clause. Because the test is not required by the regulations,

there is no regulatory limit on faceseal leakage. Leidel contends that the limit should be 1%. This contradicts his 1992 document titled "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists," NIOSH's 1987 NPRM, and his own 1992 draft revision to 30 CFR 11.

On page 51 of his 1992 document, Leidel states "The Institute conducted a statistical analysis of some published and unpublished studies to evaluate the value of 10%-maximum face-seal leakage that is the accepted value for professional practice for non-powered, air-purifying halfmasks." In fact, the premise used throughout the entire document, including the basis for his conclusions on page 129, is that the maximum acceptable faceseal leakage for a half mask is 10%.

The inherent contradictions in the claims he makes can be clarified by comparing the revision to 30 CFR 11 proposed by NIOSH in 1987 and Leidel's 1992 proposed draft of a second NPRM. Both contain sections that lay out minimum levels of acceptable fit for certified respirators. Both state that the new requirements will improve the level of fit in certified respirators. The 1987 NPRM lists the maximum allowable faceseal leakage as 5% for a half mask respirator. In his 1992 draft, Table T in the preamble establishes a maximum allowable faceseal leakage of 10%. This improved minimum level of protection is five to ten times less protective than the level that Leidel claims was in effect in 1987.

Leidel now contends that 1% faceseal leakage is the maximum level acceptable for NIOSH certification as this is the maximum level of leakage allowed for a wearer when selecting a halfmask respirator for use in the workplace. 3M agrees that a 1% faceseal leakage test requirement is appropriate for a wearer when selecting a halfmask respirator for use in the workplace. The great variation in facial shapes and sizes ensures that no single model of respirator will fit all faces. This is recognized by NIOSH and by Leidel, who acknowledges that "NIOSH does not intend that a certified respirator must be capable of providing an APF-level fit to every potential user."

Therefore, because not every potential user must obtain an assigned protection factor level fit from every certified respirator and because there is no fit test requirement in 30 CFR 11 and thus no regulatory limit on faceseal leakage, the corn oil quantitative fit test conducted by NIOSH under the General Duty clause is a valid exercise of the agency's certification authority. NIOSH acted appropriately in certifying respirators using the corn oil fit test. Therefore,

Leidel is incorrect when he asserts that the 3M 9970 has an invalid certification that should be revoked.

II. Absence of Reliable Fit Check

Leidel makes two allegations concerning the "Fit Check" or Pressure Tightness test:

1. That NIOSH personnel made procedural errors in conducting the pressure tightness test.
2. That disposable respirators cannot be successfully fit checked.

The allegation is made by Leidel that NIOSH personnel made procedural errors in conducting the pressure tightness test and should have used the test as described by the BOM in the regulations in use prior to the assumption of testing by NIOSH. The BOM test is more specific, listing that a fit check be performed with 15-20 people who are not to detect the leakage of air. In the regulation as it currently exists, NIOSH does not list any specific requirement. The agency has been using a single person to try a fit check according to the manufacturer's instructions.

The current regulation (30 CFR part 11) as it exists today has been through the proper promulgation process. Since no specific test is listed, there is no reason to perform the test as was previously detailed by the BOM.

Leidel implies that respirators certified without having gone through a rigorous test to determine their ability to be fit checked are defective in some manner. This is incorrect. The requirement for a "fit check" as described by Leidel assumes that testing of the fit on a panel of people during certification will result in improved fit on individuals.

Fit checking is an important part of respirator use. ANSI, OSHA, and the American Industrial Hygiene Association all recommend the use of a fit check to determine if a respirator about to be used is functioning properly. The use of a fit check as part of certification does not assure that an individual about to use a respirator will achieve adequate protection.

However, an important part of certification would be the determination that the manufacturer's instructions for fit checking are easily understood and can be performed. This apparently is what NIOSH has been doing for the last 22 years.

In Appendix B of Leidel's August 24, 1994 submission to the docket Mr. Leidel addresses fit checking performed on 3M disposable respirators. Leidel contends that these respirators cannot be fit checked and therefore should have their certification revoked. We disagree.

3M Attachment 3 is a study that was designed to compare the relative efficacy of the fit checking procedures of disposable (filtering facepiece) and elastomeric facepieces. The study was performed after the District of Columbia Court of Appeals ruled in 1987 that there was no evidence that fit checks performed on disposable respirators were effective. The court was correct in that there was no evidence regarding the efficacy of fit checks on disposable respirators. Likewise, there was no evidence of the efficacy of fit checks on elastomeric half mask respirators, an issue on which the court was not asked to rule.

The study was performed on both elastomeric and filtering facepiece respirators as the procedures for each differ slightly. With elastomeric respirators, success or failure is determined by whether or not a slight positive or negative pressure is maintained within the facepiece. With filtering facepiece respirators, this determination is based on whether or not an air leak is detected between the facepiece and the wearer's face.

The study found that the fit checks used on disposable, filtering facepiece respirators are at least as effective - and in some cases more effective - at detecting poor-fitting respirators as the fit checks used on elastomeric respirators. The study also showed that both the positive and negative pressure fit check methods were generally able to detect leaks that would result in fit factors below the assigned protection factor of 10 for this class of respirator. In this study, Myers concludes that:

> *"Fit check methods applied to the DFF respirators were found to be equivalent to the fit check methods applied to the EF respirator by all criteria used in the study to assess fit checks. The sensitivity of the fit check to detect bad donnings of previously fit tested respirators averaged 96% for all four respirators. Conversely, the percent of subjects accurately identifying properly donned respirators with the fit check averaged 66% for all four respirators. Considering that fit check methods are very simple to perform and require no ancillary equipment, the sensitivity and specificity for these methods are remarkably good. "*

In his comments, however, Leidel makes selective use of the data contained in 3M Attachment 3. In his Appendix B, Leidel performed beta-error analysis on 3M fit-check methodologies as applied to 3M disposable respirators. He chose

not to perform the beta analysis on the elastomeric facepiece data contained in 3M Attachment 3. Such analysis would have shown the two to be equivalent and would have forced him to conclude, using his own logic system, that elastomerics also cannot be fit checked. This would have undermined his contention that only the 9970 should be decertified because disposable respirators cannot be fit checked. According to Leidel's logic, all half mask respirators would then be deemed incapable of fit checking and have to be decertified.

Further undermining his assertion that disposable respirators should be decertified because they alone cannot be fit checked is a statement Leidel made on page 401 of his 1992 draft NPRM. The proposal noted that "NIOSH recognizes that many current negative-pressure respirators are designed to permit a 'crude' estimation by the wearer of hazardous face-seal leakage under negative- and positive-pressure conditions. NIOSH agrees that respirators designed to facilitate those types of 'fit checks' are necessary. However, performance requirements for these fit checks have not been established. It is not possible for NIOSH to require a respirator characteristic for an unspecified performance standard."

The American National Standards Institute (ANSI) Standard Z88.2 (1992) defines a fit check as "A test conducted by the wearer to determine if the respirator is properly seated to the face." ANSI Z88.2 (1992) defines a fit test, on the other hand, as "The use of a challenge agent to evaluate the fit of a respirator on an individual."

The use of fit tests and fit checks is further defined in Section 4.5.6 of the ANSI standard as follows: "Each person shall be fit tested before being assigned a tight fitting respirator. Each person using a tight fitting respirator shall conduct a fit check of the respirator by appropriate means each time the respirator is donned or adjusted." Section A.6 of the same standard ends by saying "NOTE - Fit checks are not substitutes for qualitative or quantitative fit tests." The American Industrial Hygiene Association Respiratory Protection Manual notes that: "The fit check is not a substitute for a fit test; rather its purpose is to determine if the respirator is functioning properly at the time it is being worn."

Leidel misleads the reader when he references ANSI Z88.2 procedures for fit checking respirators. The standard states that fit tests should be conducted by following "the procedures recommended by the manufacturer or by any of the checks described in A.6.1-A.6.3" and outlines the positive- and negative-pressure fit check methods used for elastomeric respirators.

The ANSI standard calls for caution when using a positive- or negative-pressure fit check because assessing the pass/fail criteria of a pressure build-up within the respirator will be "difficult or impossible to carry out on valveless [filtering facepiece] respirators." The proper pass/fail criteria for disposable respirators should be the detection of air leaks at the sealing edge, rather than the buildup of pressure within the respirator.

III. Threats to Health Care Workers

Mr. Leidel's contention that the 9970 filter media may deteriorate when used in health care settings is unfounded. Granted, electrostatic filter media have been shown to degrade in certain situations when exposed to excessive levels of dioctyl phthalate (DOP). DOP is not a commonly used oil in industrial situations, much less in a hospital or other health care setting.

It is impossible to envision any condition in a health care setting where DOP or any similar oily mist or other substance could possibly be present in concentrations that would cause filter degradation. Leidel's assertion that the possibility of filter degradation in health care workplaces presents a risk to exposed workers in those settings is totally unrealistic and not supported by any data or studies.

In addition, Leidel cites test results that he alleges indicate that DSR has failed to alert the public to "hidden hazards and deficiencies" of electrostatic filter media. In fact, he is referencing testing according to the proposed 42 CFR 84 criteria that was conducted on respirators certified under the 30 CFR 11. His allegations that 3M's 9970 and 2040 respirators should be decertified based on the results of these tests again miss the point and are misleading. 3M's approved respirators meet or exceed all current NIOSH certification criteria.

IV. Conclusion

In our many years working with NIOSH, we have found the agency certification process to be fair and scientifically credible. The 3M Company has long been committed to working with NIOSH, OSHA and other federal and state agencies, along with labor and industry, to help develop, standardize and bring to market workplace protection products that help ensure worker safety effectively and economically.

The 3M 9970 meets or exceeds all current NIOSH certification requirements, and has been extensively field tested in the workplace by 3M technical services experts. Moreover, independent academic studies of the 9970 have consistently verified the safety and efficacy of this filtration system.

3M strongly believes that Nelson Leidel's claims are totally without substance and believes NIOSH has acted and continues to act with the health and safety of the American worker as it foremost mission. It is regrettable that Leidel has taken his dispute with NIOSH and the procedural errors that he alleges have occurred within the Division of Safety Research and expanded it to attempt to blemish the reputation of 3M respirators. Although 3M would prefer to remain on the sidelines of what we see as an internal agency deliberation, we feel obliged to respond to the particular allegations that Leidel has made against our products.

Sincerely yours,

Katherine E. Reed

Katherine E. Reed, Ph.D.
Technical Director
Occupational Health and Environmental Safety Division

Attachments - 3

ATTACHMENT # 1

QUALITATIVE FACEPIECE FIT TEST

Christopher Coffey

July 30, 1982

1. Where an applicant specifies a facepiece size of sizes for the respirator together with approximate measurements of faces that the respirators are designed to fit, the Institute will provide test subjects to suit such facial measurements.

2. The facepiece will be donned according to the applicant's instructions.

3. The facepiece fit using positive or negative pressure recommended by the applicant and described in his instructions will be used before each test.

4. Each wearer will enter a chamber containing 100 ppm isoamyl acetate vapor for half mask facepieces or 1,000 ppm isoamyl acetate vapor for full facepieces.

5. Each wearer will remain in the chamber as outlined below:

Type of respirator	Time (min)	Activities	Reference
a. for protection against fumes having an air contamination level not less than 0.05 mg/m^3	2	Standing	11.140-1
b. high efficiency	5	(i) two minites walking, nodding, and shaking head in normal movements (ii) three minutes exercising and running in place.	11.140-2
c. chemical cartridge or gas mask	8	(i) two minutes nodding and turning head (ii) two minute calisthenic arm movements (iii) two minutes, running in place (iv) two minutes pumping with a tire pump into a 28-liter container	11.162-3

6. A maximum of one wearer will be allowed to detect the odor of isoamyl acetate.

ATTACHMENT # 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for Occupatior
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505–2888

Our Reference: TN03847

September 4, 1987

Mr. Donald Wilmes
3M Company
3M Center; Bldg. 260-3-02
St. Paul, Minnesota 55144

Reference: Your letters of July 16 and July 22, 1987

Subject: Request for approval of the International version of the 9970M and 9970L disposable half mask respirators

Dear Mr. Wilmes:

Approval TC-21C-438 is granted to cover the 9970M and 9970L disposable half mask respirators for respiratory protection against dusts, fumes and mists having a time weighted average less than 0.05 milligram per cubic meter, asbestos containing dusts and mists and radionuclides.

The following limitations apply to this approval:

Not for use in atmospheres containing less than 19.5 percent oxygen.

Not for use in atmospheres immediately dangerous to life or health.

Follow the manufacturer's instructions for discarding the respirator.

This respirator shall be selected, fitted, used and maintained in accordance with the Mine Safety and Health Administration, Occupational Safety and Health Administration, and other applicable regulations.

In making renewals or repairs, parts identical with those furnished by the manufacturer under the pertinent approval shall be maintained.

The approved assembly consists of the following 3M parts: 9970M and 9970L (TC-21C-438) respirators. These parts are to be marked with the indicated numbers in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

The enclosed approval label designs are to be used in preparing the approval labels. Designs of your labels must be submitted to NIOSH for approval before printing, and proofs of the printed labels must be submitted to NIOSH for further approval before their final production.

Your quality control plans for the 9970M and 9970L respirators were reviewed by NIOSH. On the basis of that review, your quality control plan is accepted as a part of this approval.

Your drawing lists dated 7-16-87 for the 9970M and 9970L respirators apply to this approval.

This Certificate of Approval is not an endorsement of the respirator by the Mine Safety and Health Administration or the National Institute for Occupational Safety and Health, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the product has met the requirements of 30 CFR Part 11.

Any changes you wish to make to this respirator shall be submitted, and a modification of this approval shall be granted before any changes are made. (Reference: Part 11, Section 11.35.)

Please submit samples of respirator packaging, bearing all required labels, instructions, and markings, for our approval, before adopting them. Please send us three 9970 respirators to be made a part of the record of this approval. We shall retain several other items as additional record material. All other material will be discarded unless we are otherwise advised by you.

Sincerely yours,

Kenneth P. Klouse, Chief,
Quality Assurance Division
Approval and Certification Center
MSHA

Nancy J. Bollinger, Chief
Certification Branch
Division of Safety Research
NIOSH

Enclosures

PERMISSIBLE RESPIRATOR FOR DUSTS, FUMES, MISTS AND RADIONUCLIDES

3M CONFIDENTIAL

United States Department of Labor
MSHA
Mine Safety and Health Administration

U.S. Department of Health and Human Services
Centers for Disease Control
NIOSH
National Institute for Occupational Safety and Health

Mine Safety and Health Administration
National Institute for
Occupational Safety and Health

APPROVAL NO. TC-21C -438

Issued To

Minnesota Mining and Manufacturing Company
St. Paul, Minnesota, U.S.A.

LIMITATIONS

Approved for respiratory protection against dusts, fumes and mists having a time-weighted average less than 0.05 milligrams per cubic meter, radionuclides and asbestos containing dusts and mists.

Not for use in atmospheres containing less than 19.5 percent oxygen.
Not for use in atmospheres immediately dangerous to life and health.
Not for use in atmospheres containing toxic gases or vapors.

CAUTION

This respirator shall be selected, fitted, used, and maintained in accordance with Mine Safety and Health Administration, Occupational Safety and Health Administration, and other applicable regulations. Follow manufacturer's instructions for discarding the respirator.

MSHA-NIOSH APPROVAL TC-21C -438
Issued to Minnesota Mining and Manufacturing Company

effective 4/1/1987

FOR DUSTS, FUMES, MISTS RADIONUCLIDES AND ASBESTOS CONTAINING DUSTS AND MISTS

The approved assembly consists of the following 3M part number 9970/ (TC-21C-438) respirator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for Occupation
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505–2888

Our Reference: TN03846

September 4, 1987

Mr. Donald Wilmes
3M Company
3M Center; Bldg. 260-3-02
St. Paul, Minnesota 55144

Reference: Your letters of July 16 and July 22, 1987

Subject: Request for approval of the U. S. version of the 9970M and 9970L disposable half mask respirators

Dear Mr. Wilmes:

Approval TC-21C-437 is granted to cover the U. S. version of the 9970M and 9970L disposable half mask respirators for respiratory protection against dusts, fumes and mists having a time weighted average less than 0.05 milligram per cubic meter and radionuclides.

The following limitations apply to this approval:

Not for use in atmospheres containing less than 19.5 percent oxygen.

Not for use in atmospheres immediately dangerous to life or health.

Follow the manufacturer's instructions for discarding the respirator.

This respirator shall be selected, fitted, used and maintained in accordance with the Mine Safety and Health Administration, Occupational Safety and Health Administration, and other applicable regulations.

In making renewals or repairs, parts identical with those furnished by the manufacturer under the pertinent approval shall be maintained.

The approved assembly consists of the following 3M parts: 9970M or 9970L (TC-21C-437) respirators. These parts are to be marked with the indicated numbers in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

The enclosed approval label designs are to be used in preparing the approval labels. Designs of your labels must be submitted to NIOSH for approval before printing, and proofs of the printed labels must be submitted to NIOSH for further approval before their final production.

Your quality control plans for the 9970M and 9970L respirators were reviewed by NIOSH. On the basis of that review, your quality control plan is accepted as a part of this approval.

Your drawing lists dated 7-16-87 for the 9970M and 9970L respirators apply to this approval.

This Certificate of Approval is not an endorsement of the respirator by the Mine Safety and Health Administration or the National Institute for Occupational Safety and Health, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the product has met the requirements of 30 CFR Part 11.

Any changes you wish to make to this respirator shall be submitted, and a modification of this approval shall be granted before any changes are made. (Reference: Part 11, Section 11.35.)

Please submit samples of respirator packaging, bearing all required labels, instructions, and markings, for our approval, before adopting them. Please send us three 9970 respirators to be made a part of the record of this approval. We shall retain several other items as additional record material. All other material will be discarded unless we are otherwise advised by you.

Sincerely yours,

Kenneth P. Klouse, Chief,
Quality Assurance Division
Approval and Certification Center
MSHA

Nancy J. Bollinger, Chief
Certification Branch
Division of Safety Research
NIOSH

Enclosures

PERMISSIBLE RESPIRATOR FOR DUSTS, FUMES, MISTS AND RADIONUCLIDES

3M CONFIDENTIAL

United States Department of Labor
MSHA
Mine Safety and Health Administration

U.S. Department of Health and Human Services
Centers for Disease Control
NIOSH
National Institute for Occupational Safety and Health

Mine Safety and Health Administration
National Institute for
Occupational Safety and Health

APPROVAL NO. TC-21C- 437

Issued To

Minnesota Mining and Manufacturing Company
St. Paul, Minnesota, U.S.A.

LIMITATIONS

Approved for respiratory protection against dusts, fumes and mists having a time-weighted average less than 0.05 milligrams per cubic meter and radionuclides.

Not for use in atmospheres containing less than19.5 percent oxygen.

Not for use in atmospheres immediately dangerous to life and health.

Not for use in atmospheres containing toxic gases or vapors.

CAUTION

This respirator shall be selected, fitted, used, and maintained in accordance with Mine Safety and Health Administration, Occupational Safety and Health Administration, and other applicable regulations. Follow manufacturer's instructions for discarding the respirator.

MSHA-NIOSH APPROVAL TC-21C - 437
Issued to Minnesota Mining and Manufacturing Company

September 4, 1987

FOR DUSTS, FUMES, MISTS AND RADIONUCLIDES

The approved assembly consists of the following 3M part number 9970 (TC-21C- 437) respirator

mon 9970L

TN03846 & TN03847
Christopher Coffey
September 4, 1987

3M's 9970 Respirator

Background:

On July 16, 1987, 3M requested aproval of their 9970 disposable half mask respirator for dusts, fumes and mists having a time weighted average less than 0.05 milligram per cubic meter and radionuclides. 3M also requested asbestos containing dusts and mists on the 9970 for international sale (these will have a different approval number).

Tests:

A. DOP for Single Filters

1. Three cartridges will be tested in an atmospheric concentration of 100 micrograms of dioctyl phthalate per liter of air at continuous air flow rates of 32 Lpm and 85 Lpm for a period of 5 to 10 seconds.

2. The DOP leakage concentration cannot exceed 0.03 percent.

B. Facepiece test (11.162-3)

1. Where an applicant specifies a facepiece size or sizes for the respirator together with approximate measurements of faces that the respirators are designed to fit, the Institute will provide test subjects to suite such facial measurements.

2. Each wearer will enter a chamber containing 100 ppm isoamyl acetate vapor for half-mask facepieces.

3. Each wearer will remain in the chamber for 8 minutes while performing the following activities:

a. Two minutes, nodding and turning head;
b. two minutes, calisthenic arm movements;
c. two minutes, running in place;
d. two minutes, pumping with a tire, pump into a 28-liter container.

4. One test subject will be allowed to detect the odor of isoamyl acetate as per policy memo, Nancy Bollinger, Assistant Chief, TCB.

C. Silica Dust for Replaceable Filters 11.140-4

1. Resistance to air flow will be measured before and after test (11.140-9).

2. Three completely assembled respirators will be tested at a continuous airflow rate of 32 Lpm.

3. The relative humidity in the chamber will be 20-80 percent and the room temperature will be approximately 25°C.

4. The test concentration in the chamber will not be less than 50 nor more than 60 milligrams of silica dust per cubic meter.

5. The particle size distribution of the silica dust will have a geometric mean of 0.4 to 0.6 micrometer, the geometric standard deviation will not exceed 2.

6. The test will last 90 minutes with samples of the concentration taken every 30 minutes.

7. The total amount of leakage shall not exceed 1.5 milligrams.

D. Exhalation Valve Leakage Test

1) Dry exhalation valves and valve seats will be subjected to a suction of 25 mm water-column height while in a normal operating position.

2) Leakage between the valve and valve seat shall not exceed 30 milliliters per minute.

E. Corn Oil Fit Test

1. Manufacturer's instructions are used for donning and checking fit of the respirator.

2. The wearer enters a hood having a concentration of 15 $\pm$ 2.5 mg/m^3 NaCl having a mean diameter of 0.6 $\pm$ 0.12 microns and a relative humidity of 50 $\pm$ 10 percent (at 25 $\pm$ 2.5°C).

3. Five minutes are spent in the chamber walking in place, turning head, and dipping chin.

4. Maximum allowable leakage during a 5 minute test is 10 percent.

Results:

A. DOP

Respirator	Leakage (%)	Flowrate (LPM)
A	0.007	85
B	0.010	85
C	0.004	85
A	0.014	32
B	0.018	32
C	0.006	32

Overall Results - Pass

B. Qualitative Facepiece Fit

Subject	Pass/Fail
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Fail
9	Pass
10	Pass

Overall Results - Pass

C. Silica Dust - see accompanying table

D. Exhalation Valve Leakage

Valve	Leakage (mL/min.)
1	0.0
2	0.0
3	0.0

Overall Results - Pass

E. Quantitative Fit Test

1	0.73
2	0.76
3	1.07
4	1.20
5	0.73
6	0.94
7	0.70
8	2.4
9	0.84
10	0.73

Recommendation:

I recommend the 9970 be approved.

References:

1. Application Letter, D. Wilmes, 7-16-87
2. 30CFR11
3. QA Acceptance, T. Pettit, 9-3-87

TN03846 3M 9970 Disposable HE

Test #/Mask	Inhalation Resistance (mm of H_2O) Maximum Allowable Initial	Final	Test Results Initial	Final	Exhalation Resistance (mm of H_2O) Maximum Allowable	Test Results Initial	Final	Chamber Concentration (mg/m^3)	Chamber Humidity (% RH)	Leakage Test Maximum Allowable	Results (mg)	Overall Results	Test Type
2625A/A	30	50	25.4	30.7	20	8.9	9.4	58.0	55%	1.5 mg	0.1	Pass	Silica Dust
2625A/B	30	50	25.4	30.5	20	7.6	8.4	58.0	55%	1.5 mg	0.0	Pass	Silica Dust
2625B/A	30	50	24.9	30.5	20	8.1	9.1	57.1	55%	1.5 mg	0.1	Pass	Silica Dust

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for Occupatic
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505–288

Our Reference: TN 04037

December 10, 1987

Mr. Donald P. Wilmes
3M Company
3M Center
Building 260-03-02
St. Paul, MN 55144

Reference: Your letter of November 23, 1987

Subject: Extension of Approvals TC-21C-437 and TC-21C-438

Dear Mr. Wilmes:

Extensions of approvals TC-21C-437 and TC-21C-438 are granted to cover an alternate foam, a reduction in the hole size in face ring, an updated specification for the filter web, correct typo on noseclip inventory number, packaging specified, and put NIOSH approval number on valve cap, valve label and in QA inspections.

Your drawing lists dated 11/23/87 for the 9970M and 9970L respirators apply to these extensions of approvals.

Your revised quality control plan for the above respirators was reviewed by NIOSH. On the basis of that review, the quality control plan is accepted as part of these extensions of approvals.

Please submit samples of respirator packaging, bearing all required labels, instructions, and markings, for our approval, before adopting them. We shall retain several items as record material. All other material will be discarded unless we are otherwise advised by you.

Sincerely yours,

Nancy J. Bollinger, Chief
Certification Branch
Division of Safety Research

3M

Highly Restricted

Name NIOSH

ITEM 16

CURRENT SUBMITTAL SUMMARY

DATE 11/23/87

NIOSH APPROVAL NUMBER	AFFECTED MODELS (EXTENSIONS)	DELETED MODELS	DATE OF LATEST PARTS LIST	MODIFICATION	DESCRIPTION (SEE LEGEND)	LATEST REVISION
TC-21C-437	9970M, 9970L	N/A	11/23/87	Alternate foam, reduce hole size in face ring. Update spec. for filter web. Correct typo on noseclip inventory number. Packaging specified. Put NIOSH approval number on valve cap, valve label, and in QA inspections.	DFMR	7/22/87

Don Wilms

AUTHORIZED BY

LEGEND: DFMR (Dust, Fume, Mist, Radionuclides)
DFMRA (Dust, Fume, Mist, Radionuclides, Asbestos Containing Dust Mi

3M CONFIDENTIAL

TN04037
Christopher Coffey
December 10, 1987

3M's 9970 Respirator

Background:

On November 23, 1987, 3M requested extensions of approvals TC-21C-437 and TC-21C-438 for the 9970M and 9970L disposable high efficiency respirators to cover an alternate nose foam, and a reduction in the hole size in face ring and other minor revisions.

Tests:

A. Facepiece fit test (11.162-3) Half Mask

1. The facepiece fit using positive or negative pressure recommended by the applicant and described in his instructions will be used before each test.

2. Each wearer will enter a chamber containing 100 ppm isoamyl acetate vapor for half-mask facepieces.

3. Each wearer will remain in the chamber for 8 minutes while performing the following activities:

a. Two minutes, nodding and turning head;
b. two minutes, calisthenic arm movements;
c. two minutes, running in place;
d. two minutes, pumping with a tire pump into a 28-liter container.

4. One wearer will be allowed to detect the odor of isoamyl acetate as per policy memo, Nancy Bollinger, Assistant Chief, TCB.

Results:

A. Facepiece Fit

Subject	Pass/Fail
1	Pass
2	Pass
3	Pass
4	Pass
5	Pass
6	Pass
7	Pass
8	Pass
9	Pass
10	Pass

Overall Results - Pass

Recommendation:

I recommend the extensions of approvals be granted.

References:

1. 30CFR11
2. Application Letter, D. Wilmes, 11-23-87
3. QA Acceptance, T. Pettit, 12-10-87

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Our Reference: TN 04321

Centers for Disease Control
National Institute for Occupation
Safety and Health – ALOSH
944 Chestnut Ridge Road
Morgantown, WV 26505–2888

August 25, 1988

Mr. Donald P. Wilmes
3M Company
3M Center
Building 260-03-02
St. Paul, MN 55144

Reference: Your letter of July 20, 1988

Subject: Extensions of Approvals TC-21C-437 and TC-21C-438

Dear Mr. Wilmes:

Extensions of approvals TC-21C-437 and TC-21C-438 are granted to cover alternate foams for faceseal, insert added to packaging, and the updating of the specifications for the plastic bag, valving process, noseclip, preform and filter assembly.

Your drawing lists dated July 20, 1988, for the 9970M and 9970L respirators apply to these extensions of approvals.

Your revised quality control plan for the above respirators was reviewed by NIOSH. On the basis of that review, the quality control plan is accepted as part of these extensions of approvals.

Sincerely yours,

FOR Nancy J. Bollinger, Chief
Certification Branch
Division of Safety Research

Enclosure

TN 04321
Christopher Coffey
August 25, 1988

3M's 9970 respirator

Background
On July 20, 1988, 3M requested extensions of approvals TC-21C-437 and TC-21C-438 for their 9970M and 9970L disposable high efficiency respirators to cover the use of two alternate foams for faceseal.

Tests
A. Facepiece test (11.162-3)

1. Where an applicant specifies a facepiece size or sizes for the respirator together with approximate measurements of faces that the respirators are designed to fit, the Institute will provide test subjects to suite such facial measurements.

2. Each wearer will enter a chamber containing 100 ppm isoamyl acetate vapor for half-mask facepieces.

3. Each wearer will remain in the chamber for 8 minutes while performing the following activities:

a. Two minutes, nodding and turning head;
b. two minutes, calisthenic arm movements;
c. two minutes, running in place;
d. two minutes, pumping with a tire, pump into a 28-liter container.

4. One test subject will be allowed to detect the odor of isoamyl acetate as per policy memo, Nancy Bollinger, Assistant Chief, TCB.

Results

Subject	Foam A	Foam B
1	Pass	Pass
2	Pass	Pass
3	Pass	Pass
4	Pass	Pass
5	Pass	Pass
6	Pass	Pass
7	Pass	Pass
8	Pass	Pass
9	Pass	Pass
10	Pass	Pass

Overall results: Pass

Recommendation
I recommend the extensions of approvals be granted.

References
1) 30 CFR 11
2) Application letter, D. Wilmes, 7-20-88
3) QA acceptance, T. Pettit, 8-24-88

ATTACHMENT # 3

EFFECTIVENESS OF FIT CHECK METHODS ON HALF MASK RESPIRATORS

Warren R. Myers[1], Majid Jaraiedi[1] and Lynnette Hendricks[2]

[1] College of Engineering, West Virginia University, Morgantown, WV;

Abstract

Studies were conducted to evaluate whether a positive/negative (+/-) fit check was an effective aid in helping user's of respiratory protective equipment (RPE) achieve a good fit when donning the RPE. Two types of half-facepiece RPE were used in the studies - the disposable, filtering facepiece and the elastomeric facepiece. Three models of disposable, filtering facepiece and one model dual-cartridge, elastomeric facepiece were evaluated.

A population of 64 inexperienced user's of RPE was randomly divided into two equal groups. One group was trained to don the RPE using the +/- fit check as an aid, while the second group was trained to don the RPE without conducting a +/- fit check. The number of successful RPE donnings achieved in the group using the aid of a fit check was compared to the number of successful RPE donnings achieved in the group not using a fit check. The data obtained from this experiment suggested that, in general, fewer unsuccessful donnings and more consistent donnings, were obtained by RPE users when fit checks were used as an aid in donning both general types of RPE used in the study. This implies that a +/- fit check has value in assisting the wearer of a disposable filtering facepiece or a half mask to properly don the RPE.

On a second population of 64 inexperienced user's of RPE the pass/fail outcome of fit checks were used to measured the discriminatory power of fit checks. The subjects used the +/- fit check to discriminate whether the fit of RPE "preadjusted" by the experimenters were good or bad. Fit checks were found to be fairly useful, easy-to-learn tools for respirator wearer's to discriminate between good and poor donnings.

Key words: fit check, elastomeric respirators, disposable respirators, half facepiece respirators, donning checks, negative fit check, positive fit check

Introduction

Current regulations, standards and recommendations addressing use and selection of respiratory protective equipment (RPE) require individual users be *fit tested* as part of the selection process and also that they be able to conduct *fit checks* when donning the RPE.[1-5]

The 1980, ANSI Z88.2, American National Standard Practices for Respiratory Protection recommends that each RPE wearer undergo and pass a quantitative or qualitative fit test as part of the selection process and be required to check the seal of the respirator by appropriate means prior to entering a harmful atmosphere.[1] The standard states that to check the seal the wearer should use procedures recommended by the respirator's manufacturer or by any of several field tests subsequently described in the standard. Among the field tests listed, were a negative and or positive pressure sealing test. Historical referencing of negative and positive sealing test procedures in AIHA/ACGIH and ANSI recommendations and standards is traced in Table I.

After a worker has been fit tested and assigned a respirator, the U.S. Occupational Safety and Health Administration's RPE standard 29 CFR 1910.134(e)(5)(i) states, "...To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator. This may be done by following the manufacturer's facepiece fitting instructions".[4]

The 1992, ANSI Z88.2, American National Standard Practices for Respiratory Protection defines a "fit check" as a test conducted by the wearer to determine if the

respirator is properly seated to the face and is performed by appropriate means each time the respirator is donned or adjusted. "Appropriate means" being the procedures recommended by the manufacturer or by checks described in the standard.[3]

Based on current practice and terminology, a *fit test* is conducted to assess the fit of the RPE during the initial selection process or during follow up fit tests typically conducted at 6 month or yearly intervals. In contrast to a fit test, a *fit check* is a simpler procedure, not requiring additional equipment. The *fit check* is for the user of already properly fit RPE to use with each donning to ascertain or "check" that the RPE is properly set on the face. The appropriate understanding of a *fit check* is that it is an adjunct to the formal process of fit testing - a tool to aid with each donning of the RPE.

While the ANSI standards mention several *fit check* procedures, the authors are aware of only the positive and or negative pressure fit check procedures being commonly used or recommended by manufacturers of RPE. In general, the end-point of these tests is to be able to maintain a +/- pressure within the facepiece for a few seconds or to be able to detect face seal leakage associated with an increased +/- pressure.

To check for maintenance of negative pressure the user typically blocks off the air inlet(s), inhales sharply so that the mask collapses slightly, briefly holds the inhalation and determines if a negative pressure is maintained inside the RPE for a few seconds and/or there is no detection of inboard air coming in the face seal. The positive pressure sealing test is performed similarly. The wearer blocks off the air outlet, exhales slightly

to cause the RPE to inflate, briefly holds the exhalation and then determines if a positive pressure is maintained inside the RPE for a few seconds and/or there is no detection of outbound air exiting the face seal. These *fit checks* were described in early standards and recommendations as documented in Table 1.

Manufacturers of disposable, filtering facepiece RPE typically recommend covering the mask with both hands, exhaling, and checking for air flow between the face and the sealing surface of the respirator.

While these fit check methods are widely recommended and used there is no published research which has evaluated the efficacy of *fit checks* in aiding wearers to don RPE. Hardis et al (1983) did report on a study correlating results of a negative pressure qualitative fit test against fit factors obtained by standard quantitative fit test.[7] They reported that out of 195 passing negative pressure qualitative fit tests only one was found to provide a quantitative fit factor of less than 10.

The objective of this paper is to try and address a number of questions and issues regarding fit checks: 1) Does performing a fit check help users of properly fit RPE detect bad donnings?; 2) Does use of a fit check increase the probability of achieving a certain level of fit?; 3) Does use of a fit check provide more consistent donnings of the RPE?; and 4) Is the fit check recommended for filtering facepiece respirators as effective as those recommended for elastomeric respirators?.

This paper reports the results of two experiments. The first evaluated the usefulness of the fit check to assist subjects with correctly donning RPE by comparing

the number of successful donnings achieved in two groups - one donning with the aid of a fit check, the other without the aid of a fit check. The second experiment measured the discriminatory power of a fit check by having subjects assess the fit of RPE which had been preadjusted to cause poor fit characteristics.

Materials and Methods

Test Subjects

Subjects were recruited via questionnaire from a very large population (> 10,000) of predominantly white collar workers. All subjects had to meet the following minimum requirements to participate in the research study:

1) no direct affiliation or business responsibility with the research, design or manufacture of RPE;
2) no previous training in the use of RPE;
3) no previous experience with wearing RPE in their jobs; and
4) no facial hair that would compromise the seal of the RPE.

Potential test subjects, meeting the aforementioned criteria, were given manufacturer's instructions for donning the RPE. They were then fit tested using the Sodium Saccharin Qualitative Fit Test Method following the protocol published in the OSHA Lead Standard 29 CFR 1910.1025[8], This method has been validated against quantitative fit test methods to be capable of rejecting masks with fit factors of less than

approximately 100.[9]

If the subject failed the initial fit test the respirator was donned again and the fit test repeated. If the subject failed the fit test on the second donning, that respirator was not used by that subject in the study. Subjects failing to receive adequate fit on more than one of the four respirator set were not selected for the study.

Subjects were randomly divided into three groups. The 32 subjects assigned to group 1 were trained to don and adjust the respirators but were not instructed on using fit checks. The 32 subjects assigned to group 2 were trained to don and adjust the respirators with the aid of fit checks. Because of the fit test inclusion criteria discussed in the preceding paragraphs in some cases there were less than 32 subjects wearing each of the four respirators in these two groups.

The 64 subjects assigned to group 3 were trained to don and adjust the respirators with the aid of fit checks. This group was used in Experiment II to measure the discriminatory power of a fit check by having subjects assess the fit of the RPE which had been preadjusted to purposely cause poor fit characteristics.

Subjects selected for use in the studies received a small compensation for their participation.

Respirators

Four negative-pressure, half-facepiece respirators were used in the study. Each is certified in the United States by the National Institute of Occupational Safety and

Health (NIOSH). The assigned protection factor for half-facepiece respirators is 10.[2] Three of the RPE were different types of disposable filtering facepiece (DFF) respirators. The fourth type was a dual cartridge, elastomeric facepiece (EF) respirator.

One of the three DFF respirators was a NIOSH certified dust/mist (D/M) class device that incorporated a moldable nose clip Figure 1. The second was a NIOSH certified dust/fume/mist (D/F/M) class device that had an exhalation valve and a moldable nose clip (Figure 1). The third was a NIOSH certified high efficiency (HE) class device that had an exhalation valve, a moldable nose clip and an elastomeric face seal ring. The DFF respirators were available in only one facepiece size except for the HE, which was available in two sizes.

The EF respirator was configured with NIOSH certified D/M class filter elements. This respirator was available in two facepiece sizes.

Respirator Preadjustment for Experiment II

The moldable nosepiece on the three DFF respirators provided an opportunity to preadjust the nosepiece to purposely induce leaks around subject's noses. Oestenstad et al found that the nose is the most common leak site for subjects wearing half facepiece respirators.[10] In that study which involved 73 subjects, the nose was involved as a site of leakage approximately 78% of the time.

The nosepiece of the DFF respirators were pre-formed on one of two different head forms. One head form had a very wide smooth nose bridge which left the

nosepiece virtually unchanged from their "out of-the-package configuration". The other had a much narrower nose which resulted in the nosepiece being squeezed together during the pre-forming. These two pre-formed nosepiece configurations coupled with the range of facial sizes and nose shapes represented by the study population presented the possibility for a wide range of fit outcomes.

Pre-adjustments on the EF respirator consisted of setting the head and neck straps two centimeters looser than where the subject had initially adjusted the straps to pass the saccharin qualitative fit test. Strap length had been noted during the training session. The head cradle construction of this respirator made it possible to pre-adjust strap tension for this phase of the testing while still enabling the subjects to easily don the respirator. In addition, each subject wore both sizes of the EF respirator, resulting in an even greater range of fits.

Laboratory Protection Factor (LPF) Testing

The quality of each donning was assessed from measurements of particle concentrations inside and outside the respirator during a chamber test. It is important to note that since non-HEPA class filters were used (in contrast to requirements to conduct fit testing), filter penetration could be a significant contributor to the in-facepiece concentration. Therefore, the independent variable of the chamber test is denoted as a laboratory protection factor (LPF).[11] As defined for the purposes of this study, the LPF is the ratio of chamber particle concentration to in-facepiece particle concentration where

the in-facepiece concentration is a function of filter efficiency as well as face seal penetration.

Chamber testing was performed with a system that utilized a TSI Model 3450 Vibrating Orifice Aerosol Generator to produce a 2.0 μm diameter particle of corn oil. Particles were counted with a TSI Model 33 APS unit. The equipment and test setup have been previously described in greater detail.[12]

In-facepiece particle counts were determined at one second intervals and averaged over each exercise period which lasted for 0.5 minute. The exercises used were the standard six exercises suggested for quantitative fit testing of half-facepiece respirators.[1]

Chamber concentration was determined by averaging the particle counts from one-minute sampling periods immediately before and after the subject performed the six exercises.

Penetration for a particular exercise (P_j) was calculated from the average of the 30 one second in-facepiece particle counts (FPC_j) made during that particular exercise and the average chamber particle counts (CPC).

$$P_j = \frac{FPC_j}{CPC} \qquad (1)$$

The average "test" penetration was calculated as follows:

$$P_{test} = \frac{\sum_{j=1}^{n} P_j}{n} \qquad (2)$$

where j = 1st to the nth exercise

The overall "test" LPF was calculated as the inverse of the overall test penetration.

$$LPF_{test} = \frac{1}{P_{test}} \qquad (3)$$

Measurements of in-facepiece particle counts were corrected for errors introduced by retention of particles in the lung. Models for deposition of inhaled aerosols for nose and mouth breathing were used to derive the fraction of particles deposited in the lung.[13] It was assumed that subjects spent equal time nose and mouth breathing. The particle diameter of the test aerosol was ≈ 2.0 μm with a particle density of 0.91. Based on breathing patterns characteristic of sedentary work rate conditions an average flow rate of 500 ml per second was selected along with an average residence time of 2 seconds.[14,15]

Under these conditions, the models yield deposition fractions of ≈ 0.48 and ≈ 0.81 for mouth and nose breathing, respectively. Averaging these values, assuming equal time is spent nose and mouth breathing, leads to an average deposition fraction of ≈ 0.65.

When calculating the correction factor to apply to the overall breathing cycle it

was assumed that inhalation and exhalation times were equal. The deposition fraction was only applied to the exhalation portion of the breathing cycle. The resulting correction factor was 0.675. The correction factor was used as a constant that was applied to each test result. Correcting in-facepiece particle count data for lung deposition increases estimates of penetration.

The in-facepiece particle count data reflected total inboard leakage. That is, leakage through the filter and exhalation valve of the facepiece, as well as around the sealing surface of the facepiece. The magnitude of the filter and exhalation valve leakage on these respirators was estimated before testing began.

To evaluate filter efficiency, specimens of the each respirator were sealed with an air tight seal to a test form. Air was drawn through the respirator with a breathing machine operated with a 622 work rate cam which produces a tidal volume of 1.6 L. The stroke frequency was adjusted to produce a minute flow rate of approximately 30 L. The challenge aerosol was the corn oil aerosol used in performing the LPF testing. Table 2 shows the results of the filter penetration studies that were performed.

The filter penetrations of the D/F/M and HF filtering facepieces and the D/M elastomeric facepiece were very small. On these devices filter penetration would not be a major source of in-board leakage. On the D/M filtering facepiece the filter penetration was 1.25%. For this device filter penetration could be a significant contributor to total in-board leakage and thereby confound evaluation of the fit check.

Experimental Protocols

Experiment I

In experiment I, which was to evaluate fit checks as an aid to successful donning, two groups of 32 subjects, with no previous experience wearing respirators, were trained to don the four respirators following the manufacturer's instructions.

One group was trained to use fit checks as part of the donning process. The fit check outcome, i.e., "pass" or "fail" was noted. Again, manufacturer's instructions for conducting the fit checks were followed. With the EF respirator the fit check instructions were to use either a positive pressure or a negative pressure sealing test therefore, one half of the 32 subjects were randomly selected and trained on one fit check or the other.

The second group only received donning instructions, e.g., how to position the mask on the face, how to adjust the straps and how to mold the nosepiece to the nose, etc.. They received no training or instruction in conducting or using fit checks.

Subjects were trained over a two day period. Two of the four respirators were randomly selected for each day. Testing was conducted over the three days immediately following their training.

Six replicate donnings and associated LPF measurements were made on each test subject for the respirators in which they had been successfully fit tested. The respirator test order was randomized. There is a subjective factor in how a person dons a respirator and performs a fit check. This subjectivity would tend to make the 6 donnings per subject not independent. For statistical analyses, sample sizes were corrected using the

Satterthwaite method.[16] This method uses the estimates of inter and intra- subject variability to determine a modified sample size equivalent to the number of independent readings. For our data this correction reduced the sample sizes from 23-65%.

After receiving training, no attempt was made to correct donning errors made by the test subjects such as crossing straps, forgetting to tighten straps, failure to mold nosepiece, etc during the testing phase. In the group using fit checks, when the subject's assessment of the fit was solicited, no attempt was made to correct or assist in performance of the fit check. For this group, fit check instructions were available for reference if a subject cared to review them.

Experiment II

For the second experiment 64 subjects were trained to don the four respirators with the aid of the manufacturer's suggested fit check procedures. Subjects from experiment I could not participate in experiment II. The training and qualification criteria for subjects in experiment II were identical to those for the group trained to use fit checks in experiment I.

On the day following their training, subjects donned and fit checked two pre-adjusted versions of each of the four respirators. The respirators were pre-adjusted to produce a sufficient number of poor fits to test the ability of fit checks to identify poor or improper fits.

During this phase of testing, subjects were instructed to don the respirators as they normally would except they were not to reform the nosepiece of the DFF respirators

or re-adjust the straps of the EF respirator. The fit check outcome, i.e., "pass" or "fail" was noted and the subject under went the LPF testing. The outcome of the two tests were then compared.

Results and Discussion

Laboratory protection factors from the group donning respirators without fit checks were compared to the LPFs obtained from the group donning with fit checks. The fit check and no fit check groups were compared in several ways. First, log probability plots comparing the LPFs measured on each group were made for each respirator (Figures 2-5).

Figure 2 is the log - probability (L-P) plot of the LPFs for the groups donning the dust/mist filtering facepiece with and without the aid of fit checks. Each plotting point is the geometric mean (GM) LPF for each subject. The L-P distributions of the LPF values measured on subjects using and not using fit checks are very similar between the 30th and 80th percentiles. The GM LPF for the no fit check group was 93 while the group using fit checks had a GM LPF of 110. No significant difference in GM LPF was found between the two test groups.

There is evidence in Figure 2 to suggest that using fit checks did improve the LPF values at the low end of the distribution - below the 30th percentile. The use of the fit check had the effect of shifting the low end tail of the LPF distribution to the right. These observations suggest that conducting the fit check had some value in helping to

improve or eliminate poorer quality donnings. The variability in LPF measurements was not found to be significantly lower in the test group donning with the aid of fit checks (Table 4).

Figure 3 shows the L-P plot of the LPFs for the D/F/M filtering facepiece. The distribution LPF values obtained on the test group donning with fit checks fell to the right of the group not using fit checks, i.e., the group using fit checks achieved higher LPFs. The GM LPF for the no fit check group was 140 while the group using fit checks had a GM LPF of 291.

In this case the distributions were significantly different. The use of a fit check as an aid to donning this type of respirator significantly improved its overall performance in the chamber test. The variability of the two distributions was not significantly different (Table 4).

A possible explanation for the fit check causing an overall increase in the LPF distribution without changing the shape of the distribution is that performance of the fit check caused subjects to take added care during donning. The added care benefitted from doing the fit check, resulted in better donnings causing a shift of the entire LPF distribution not just the lower tail.

Figure 5 shows the (L-P) plot of the LPFs for the HE filtering facepiece. The GM LPF for the no fit check group was 758 while the group using fit checks had a GM LPF of 1633. In this case the distributions were not found to be significantly different.

The distribution of LPFs achieved with the group using fit checks was shifted

towards higher LPFs in the lower tail region. This shift resulted in a significantly lower variability than with the no fit test group (Table 4). With the HE respirator, conducting a fit check had the effect of improving the quality of respirator donnings thereby eliminating the lower LPFs.

The shift in the lower tail of the LPF distributions for the D/M and HE DFF respirators implies that performance of the fit check did not tend to improve the fitting characteristics of those respirators beyond removing poorer fits. For the D/F/M DFF respirator, performance of fit checks resulted in a significant average improvement in LPFs, not just in the lower tail of the distribution.

Figure 5 shows the L-P plot of the LPFs for the D/M elastomeric facepiece. The GM LPF for the no fit check group was 608 while the group using fit checks had a very similar GM LPF of 580. The distribution of LPF values for the two groups are very similar, indicating no improvement in the quality of donnings was achieved by doing fit checks.

A possible explanation for this observation is the small number of lower LPFs values - only 5% of each population, or 2 subjects had LPFs around 100 or less. The small number of donnings actually resulting in LPF values below 100 reduces the opportunity to observe the value of a fit check, i.e., to remove the lower LPFs. This could also explain why the characteristic shift in the tail region towards higher fit factors for the group using fit checks is not seen with this respirator but was observed with the D/M and HE DFF respirators.

An alternative explanation for this observation is that performance of fit checks were not effective at detecting poorer donnings. However this explanation is questioned by the results from Experiment II which found that performing fit checks on the EF respirator resulted in the best estimate of sensitivity for detecting poor fits.

The effect of performing the fit check on the proportion of subjects achieving LPFs greater than ten was also examined. The value of 10 represents the assigned protection factor for half facepiece respirators[1,2]. The LPF data collected in these studies were not always log-normally distributed (see Figures 2-5). As a result, binomial statistical methods were used to analyze the data collected from this phase.

The observed and corrected (Satterthwaite's correction) values of the number of donnings where resulting LPFs were less than ten are listed in Table 3. Only the corrected values were used in subsequent analysis. A binomial approximation to the hypergeometric distribution was used to compare the proportions of donnings resulting in LPFs less then ten for the test groups donning with versus without fit checks.[17]

For the HE filtering facepiece the proportion of donnings resulting in LPFs less than ten was significantly lower for the test group donning with fit checks as compared to the test group donning without fit checks. No difference was found with the other three respirators. However, the data in Table 3 does suggest that the performance of fit checks tends to lower the proportion of donnings resulting in LPFs less than ten for the D/M and D/F/M filtering facepieces.

The method of performing the fit check with the three filtering facepiece

respirators differs slightly from the fit check method for the elastomeric respirator i.e., the subject is checking for airflow around the face seal in the former and for buildup and maintenance of positive or negative pressure in the latter case. A binomial approximation to the hypergeometric distribution was used again, this time to compare the proportions of donnings resulting in LPFs less than ten for the elastomeric facepiece and the filtering facepieces.

For subjects donning with fit checks, there were no significant differences between the proportion of donnings resulting in LPFs less than ten for the elastomeric facepiece or any of the filtering facepieces (see Table III).

The effect of the fit check on the variability of LPFs achieved with multiple donnings was also examined for each respirator. The pooled standard deviations for subjects using fit checks compared to the pooled standard deviations for subjects not using fit checks is given in Table 4. The variability in LPF measurements was found to be significantly lower for subjects using fit checks with the HE filtering facepiece. No significant differences were seen in variability of LPF measurements for the other respirators. However, a slight reduction in pooled standard deviations for subjects using fit checks was observed with the D/M and D/F/M filtering facepieces.

Experiment II

This experiment was conducted to measure the discriminatory power of fit checks to differentiate between acceptable donnings (ie., those donnings resulting in LPFs of ten

or better) and unacceptable donnings (ie., those donnings resulting in LPFs less than ten). The discriminatory power of a test is determined by its specificity and sensitivity. Specificity is the ability of the test to accurately identify a correctly donned respirator. Sensitivity is the ability of the test to accurately identify an incorrectly donned respirator.

Of these two parameters, the sensitivity of the test is most important. In this case, sensitivity relates to the chance of a worker unknowingly wearing a respirator, that is not properly donned, into a hazardous environment. The specificity is not as critical since the consequence of this error is most likely that the worker will readjust a respirator that is already donned correctly. Perhaps in the process the quality of the donning will be improved.

Sensitivity of the fit check was calculated by taking the number of donnings resulting in LPFs less than ten where the subject said the respirator failed the fit check, divided by the total number of donnings which actually resulted in LPFs less than ten. For a test to have perfect sensitivity this value would be 100%. Table 5 gives the sensitivity and the 95% confidence intervals determined for each respirator. The values were corrected for sample size via the Satterthwaite formula.

The sensitivity of the elastomeric facepiece fit check procedure was not significantly different than the sensitivity of the fit check procedure used for the filtering facepieces.

Specificity was calculated by dividing the number of donnings resulting in LPFs of ten or higher, where the subject said they passed the fit check, by the total number

of donnings resulting in LPFs of ten or higher. For a test with perfect specificity, this value would be 100%. Table 6 shows the specificity determination made on each respirator corrected for sample size via the Satterthwaite formula, and the 95% confidence interval for each value. A contingency table analysis of the specificity values found that fit checks done on the D/F/M DFF respirator resulted in significantly better specificity than with the other respirators. There is no obvious explanation for this finding.

Conclusions

The laboratory protection factor results obtained from these studies found that employing a manufacturer's recommended fit check when donning a respirator helped detect and prevent poorer quality donnings of the respirator. As the quality of donnings increases the usefulness of fit checks as a tool to evaluate the donning - with the goal of further improvement - becomes less. The better the facepiece seals to the face the more difficult it is for the wearer to differentiate whether subtle changes in pressure or airflow have occurred.

Results observed on the D/M DFF respirator, suggest that when fit checks are used for donning respirators which have considerable filter penetration the resulting improvement in the quality of a donning may be considerably less important in determining the net performance. A fit check helps evaluate the integrity of the face seal. As filter leakage becomes a more significant component of total in-board leakage the

relevance of conducting a fit check decreases.

Donning respirators with fit checks did decrease the likelihood from 2.8% to 0.81% of those donnings resulting in LPF values of less than ten. However, the decrease was only statistically significant with the HE DFF respirator.

Performing a fit check was found to produce a general reduction in the variability of the LPFs measured on the three DFF respirators. The reduction was significant for one of the three.

The general trend towards fewer unsuccessful donnings and more consistent donnings, when fit checks were used, implies that fit checks have value in assisting the wearer to properly don a respirator.

Fit check methods applied to the DFF respirators were found to be equivalent to the fit check methods applied to the EF respirator by all criteria used in the study to assess fit checks.

The sensitivity of the fit check to detect bad donnings of previously fit tested respirators averaged 96% for all four respirators. Conversely, the percent of subjects accurately identifying properly donned respirators with the fit check averaged 66% for all four respirators. Considering that fit check methods are very simple to perform and require no ancillary equipment, the sensitivity and specificity for these methods are remarkably good.

Inexperienced workers can be trained in performing successful fit checks on elastomeric and disposable filtering facepiece RPE. It is expected that with additional

experience respirator users might develop better and more consistent fit check skills thereby further improving the quality of respirator donning. Therefore we conclude, that for wearers of respirators which have been properly fit by a recognized fit test, conducting fit checks as per manufacturer's instructions can be a useful tool for more consistently maintaining the quality of respirator donning.

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Table 1 Evolution of Negative and Positive Pressure Test Traced Through Select Documents.

Reference	Negative Pressure Test	Positive pressure Test
AIHA/ACGIH 1963[5]	Close off the inlet opening of the canister by covering it with the palm of hand or by replacing the tape seal, inhale so that the facepiece collapses slightly, and hold the breath for 10 sec. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the gas mask-as worn-is satisfactory.	Close off the exhalation valve and exhale gently so that a slight positive pressure is built up in the facepiece. If no outward leakage of air is detected at the periphery of the facepiece, the face fit is satisfactory.
ANSI Z88.2-1969[6]	Close off the inlet opening of the canister or cartridge(s) by covering it with the palm of the hand(s) or by replacing the seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for 10 sec. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is probably satisfactory.	Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of leakage of air at the seal. For most respirators, this method leak testing requires that the wearer first remove the exhalation valve cover and then carefully replace it after the test.
ANSI Z88.2-1980[1]	Follow procedures recommended by the manufacturer or the inlet opening of the respirator's canister(s), or cartridge(s), or filter(s) is closed off by covering with the palms of the hand(s), by replacing the inlet seal on a canister(s) or by squeezing a breathing tube or blocking its inlet so it will not allow the passage of air. Then the wearer inhales and holds his breath for at least 10 seconds. If a facepiece collapses slightly and no inward leakage of air into the facepiece is detected, it can be reasonably assured that the fit of the respirator to the wearer is satisfactory. For a respirator equipped with a mouthpiece and nose clamp, if leakage of air into the nose or mouth cannot be detected, then it can be reasonably assured the fit of the respirator to the wearer is satisfactory.	Follow procedures recommended by the manufacturer or the exhalation valve or breathing tube, or both, is closed off and then the wearer exhales gently. The fit of a respirator equipped with a facepiece is considered to be satisfactory if a slight positive pressure is built up inside the facepiece without the detection of any outward leakage of air between the sealing surface of the facepiece and the respirator wearer's face. The fit of a respirator equipped with a mouthpiece and nose clamp is considered satisfactory if the respirator wearer senses a buildup of positive pressure and is unable to detect any outward leakage of air through the nose and in the area between the mouth and mouthpiece.
ANSI Z88.2-1992[2]* * This standard carries the following caution--"Care must be taken in conducting negative or positive pressure fit checks. Thorough training in carrying out these tests should be given to respirator wearers. Fit checks are not substitutes for qualitative or quantitative fit tests."	Follow procedures recommended by the manufacturer or the inlet opening of the respirator's canister(s), or cartridge(s), or filter(s) is closed off by covering with the palms of the hand(s), by replacing the inlet seal on a canister(s) or by squeezing a breathing tube or blocking its inlet so it will not allow the passage of air. Then the wearer inhales gently and holds his/her breath. If a facepiece collapses slightly and no inward leakage of air into the facepiece is detected, it can be reasonably assured that the fit of the respirator to the wearer is satisfactory.	Follow procedures recommended by the manufacturer or the exhalation valve or breathing tube, or both, is closed off and then the wearer exhales gently. The fit of a respirator equipped with a facepiece is considered to be satisfactory if a slight positive pressure is built up inside the facepiece without the detection of any outward leakage of air between the sealing surface of the facepiece and the respirator wearer's face.

Table 2. Aerosol Penetration through Filters and Valves

Respirator	Mean Percent Penetration	N	Standard Deviation	Filter Eff. Factor[1]
D/M-DFF	1.25	6	0.153	80
D/F/M-DFF	4.50×10^{-3}	8	0.0019	22000
HE-DFF	3.90×10^{-4}	6	0.00021	256000
D/M-EF	5.48×10^{-3}	5	0.00134	18200

[1] A number inversely related to the penetration of the filter[17].

Table 3. Proportion of Donnings Resulting in Laboratory Protection Factors Less Than 10.

	No Fit Check Group Observed Values			Fit Check Group Observed Values		
Respirator	Uncorrected	Corrected[1]	% < 10	Uncorrected	Corrected[1]	% < 10
D/M-DFF	5/152	2.34/71	3.3[A]	0/132	0/87	0.0[A]
D/F/M-DFF	3/171	1.49/85	1.8[A]	0/168	0/58	0.0[A]
HE-DFF	11/150	5.79/79	7.3[A]	2/192	1.54/148	1.0[B]
D/M-EF	0/186	0/113	0.0[A]	3/186	1.68/104	1.6[A]
Average		9.62/348	2.76[A]		3.54/397	0.81[B]

1 Sample size reduced via Satterthwaite statistical method (Snedecor and Cochran, 1980).

2 Percent of donnings resulting in LPFs less than 10 between the fit check and no fit check groups with different superscripts were significantly different.

Table 4. Pooled Standard Deviations for Groups of Test Subjects Donning Respirators With and Without Performing a Fit Check Procedure.

Respirator	No Fit Check	Fit Check
D/M-DFF	.229	.211
D/F/M-DFF	.322	.295
HE-DFF[1]	.657	.519
D/M-EF	.413	.465

[1] A significant difference in variances exists between the fit check and no fit check groups.

Table 5. Sensitivity[1] Estimates Determined for Fit Checks Conducted on Four Types of Half Facepieces.

Respirator	Best Estimate[2]	95% Confidence Intervals
D/M-DFF	24.3/27 (90%)	73.4% - 97.5%
D/F/M-DFF	3.2/4 (80%)	45.0% - 96.2%
HE-DFF	23/23 (100%)	85.0% - 100%
D/M-EF[3]	31/31 (100%)	89.0% - 100%

1 Sensitivity is calculated by taking those donnings resulting in LPFs less than 10, that were identified by the test subject as a fit check failure, divided by all the donnings resulting in LPFs less than 10.

2 The observed values reported here have been corrected for sample size via the Satterthwaite formula (Snedecor, and Cochran, 1980).

3 Sensitivity value determined for the elastomeric facepiece was not significantly difference than the sensitivities observed on the disposable filtering facepieces.

Table 6. Specificity[1] Estimates Determined for Fit Checks Conducted on Four Types of Half Facepieces.

Respirator	Best Estimate[2]	95% Confidence Intervals
D/M-DFF	35.4/64 (55%)	43% - 68%
D/F/M-DFF	75.9/88 (86%)[3]	77% - 93%
HE-DFF	39.4/69 (57%)	45% - 70%
D/M-EF	36.8/64 (57%)	45% - 70%

1 Specificity is calculated by taking the number of donnings with fit factors of 10 or greater, that were fit check "passes" and divided by the total number of donnings with fit factors of 10 or greater.

2 The observed values reported here have been corrected for sample size via the Satterthwaite formula (Snedecor, and Cochran, 1980).

3 A contingency table analysis found that the specificity for this respirator is significantly better than the specificity of the other respirators.

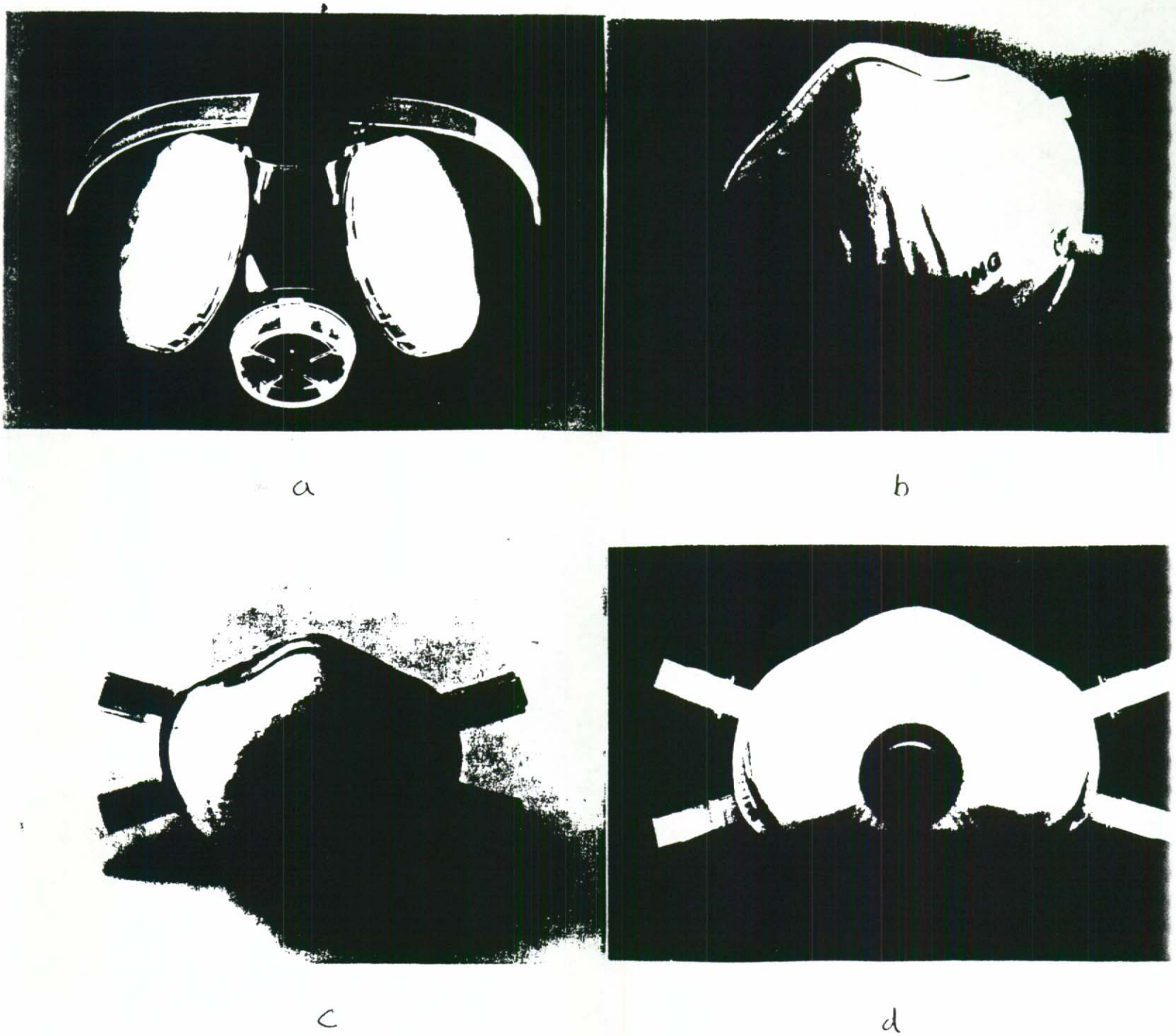
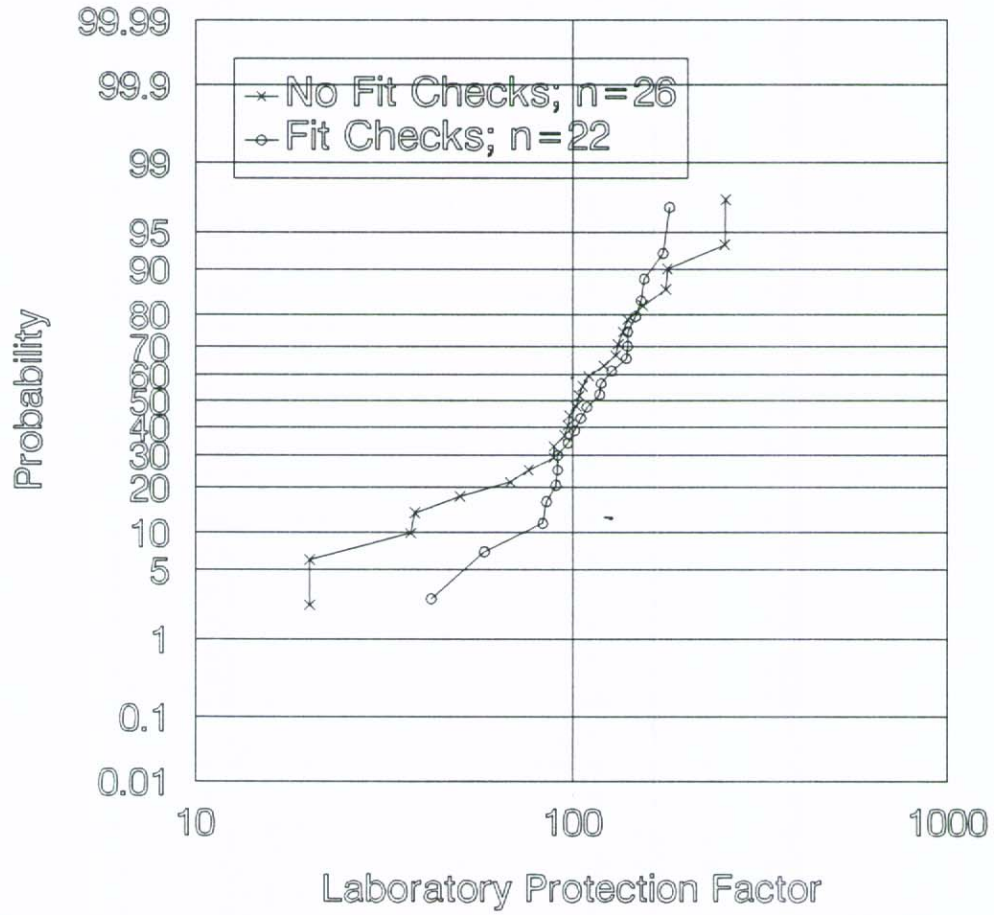


Figure 1 Photographs of test respiators a) elastomeric with dust/mist filters; b) dust/mist disposable filtering facepiece; c) dust/mist/fume disposable filtering facepiece; d) high efficiency dispoable filtering facepiece.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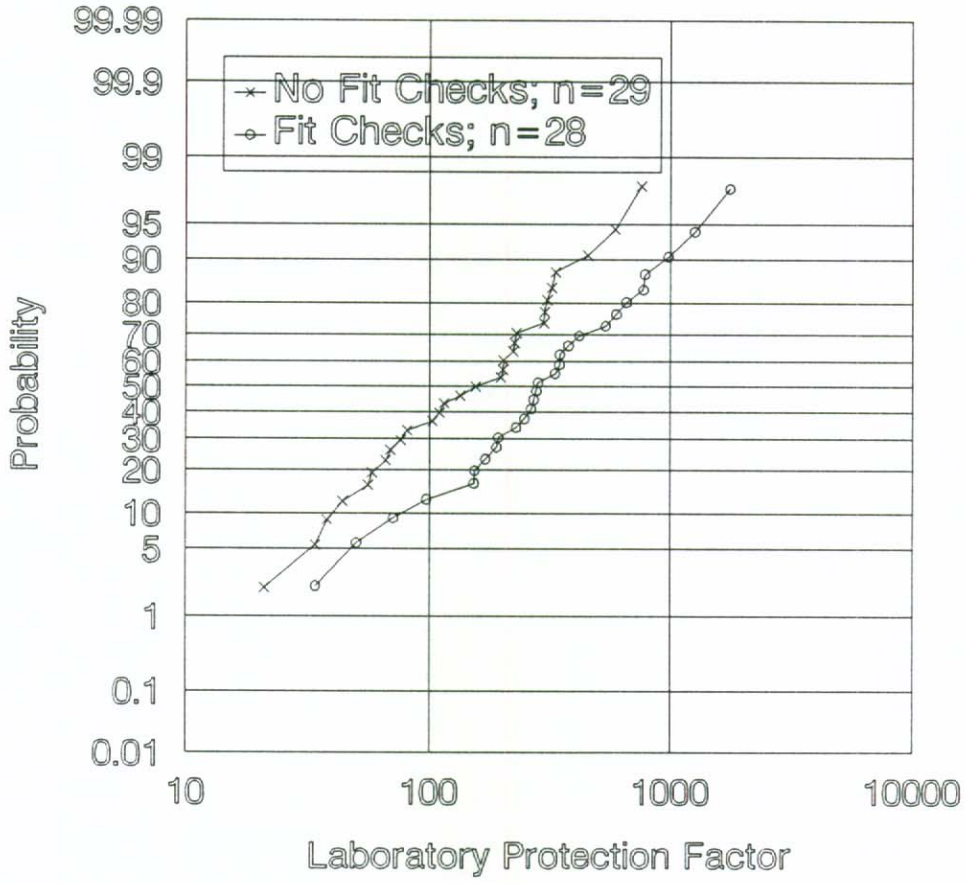
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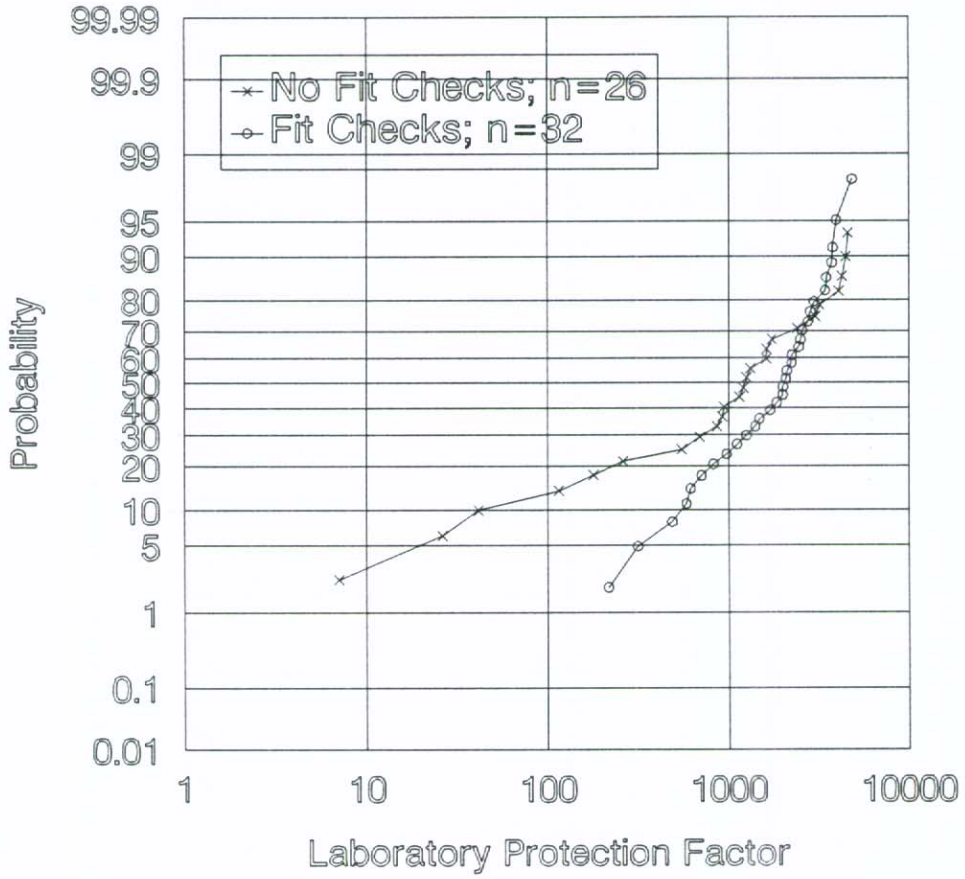
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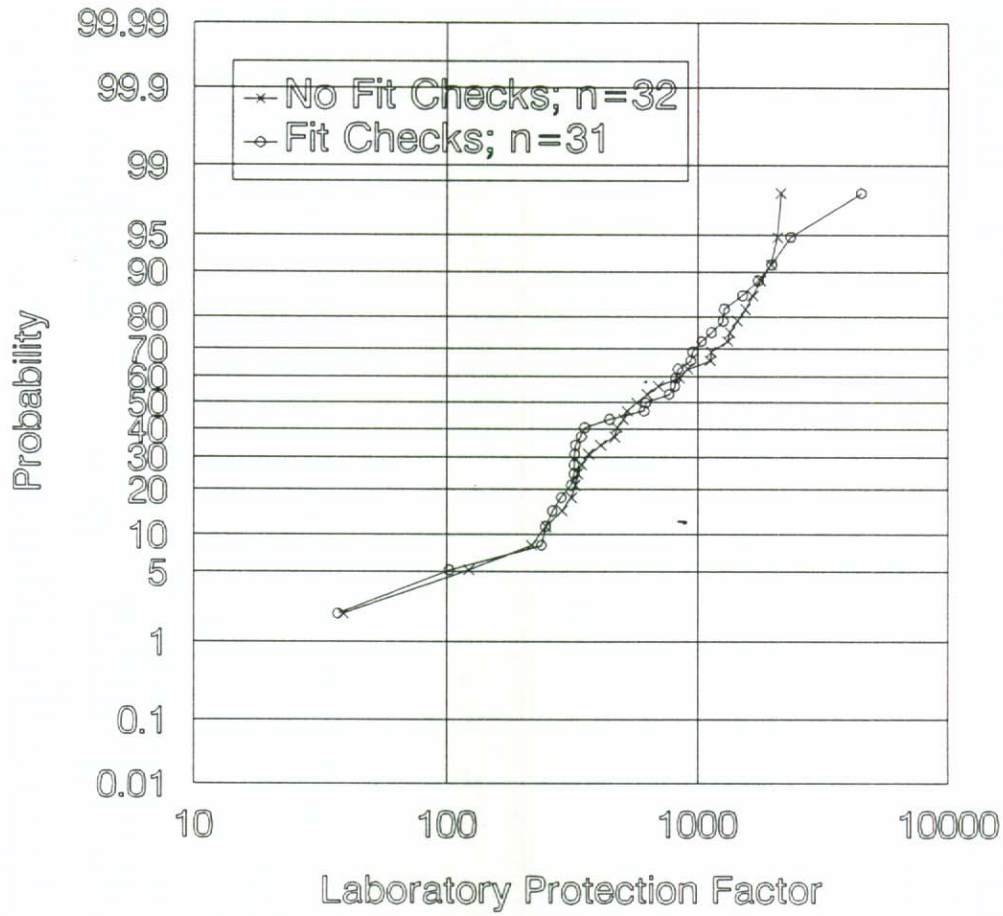
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