DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

# Memorandum

Date August 11, 1994

From Senior Science Advisor, OD, NIOSH

Subject Transmission of Personal Comments on NIOSH's 2nd NPRM for 42 CFR Part 84

To Ms. Diane Manning, PO3/C34
Docket Officer, DSDTT, NIOSH

Attached please find my 75-page analysis entitled *Comments on NIOSH's Second Notice of Proposed Rulemaking on Respiratory Protective Devices—42 CFR Part 84*. NIOSH solicited comments on this NPRM in its *Federal Register* notice of May 24, 1994 (59 FR 26850).

Please note that these comments consist solely of my individual professional analysis, conclusions, and personal recommendations. The attached comments do not necessarily reflect the conclusions and recommendations of my employer, which is the National Institute for Occupational Safety and Health. I have submitted these comments in an effort to protect several million of respirator wearers from the hidden hazards of dust/mist (DM), dust/fume/mist (DFM), and high-efficiency particulate (HEPA) filter respirators.

Because I was NIOSH program manager for the 42 CFR Part 84 NPRM over the 5-year period of September 1987 until October 1992, I believe I am in a unique position to comment on both technical and policy issues in the subject NPRM, which was developed over October 1992 to May 1994 by personnel in NIOSH's Division of Safety Research (DSR).

The nature and technology of industrial respirators prevent users and purchasers from directly assessing the *safety and efficacy* of the NIOSH-approved respirators they wear and purchase. Thus American respirator users and purchasers must trust the scientific competence and integrity implicit in NIOSH certifications. My attached comments detail how NIOSH's competence and integrity have been grievously compromised.

The Director of NIOSH holds regulatory and watchdog responsibilities for industrial respirators that are a higher duty and demand more public trust than those duties held by the Commissioner of the Food and Drug Administration (FDA) for medical devices.

About 7 to 10 million American workers use NIOSH-certified respirators at some time to protect their lives and health. Most workers must wear their NIOSH-certified respirators as an involuntary condition of employment. They have no choice but to put their trust in NIOSH-certified respirators to protect themselves against toxic and lethal workplace conditions.

NIOSH must take urgent remedial action to protect millions of American respirator users by rectifying past errors committed by DSR personnel and NIOSH management. In particular, urgent action is needed on my following major recommendations:

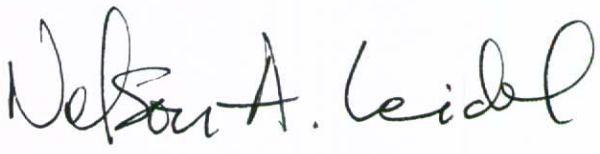
- NIOSH should immediately annul and revoke Federal approval certifications for the 3M 9970 HEPA mask.

- NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all NIOSH certifications issued for particulate-filtering respirators.

- NIOSH should immediately withdraw DSR's NPRM of May 1994.

- NIOSH should terminate all current Federal certifications for respirators and withdraw from its regulatory role as a "watchdog" agency, if the Institute is not ready, willing, or able to provide FDA-style testing and enforcement to protect American respirator users and purchasers.

Lastly, I am retiring on September 1, 1994. After that time I can be reached at 1004 Shady Valley Place, Atlanta, GA 30324, phone: (404) 233-3737.



Nelson A. Leidel, Sc.D.
CAPT, USPHS

Enclosures: (1) Comments on 5/94 NPRM (75 pages)
(2) NIOSH's 1992 NPRM Policy for Federal certification of Industrial Respirators (748 pages)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

# Memorandum

Date August 8, 1994

From Senior Science Advisor, OD, NIOSH

Subject Transmission of (1) Comments on NIOSH's 2nd NPRM for 42 CFR Part 84 and (2) Comments on Serious Problems in NIOSH's Federal Certification Program for Industrial Respirators

To Director, NIOSH

Attached please find my 75-page analysis entitled *Comments on NIOSH's Second Notice of Proposed Rulemaking on Respiratory Protective Devices—42 CFR Part 84.* NIOSH solicited comments on this NPRM in its *Federal Register* notice of May 24, 1994 (59 FR 26850). Additionally, I have provided comments on serious problems in the certification program administered by personnel in your Division of Safety Research (DSR)

Because I was NIOSH program manager for the 42 CFR Part 84 NPRM over the 5-year period of September 1987 until October 1992, I believe I am in a unique position to comment on both technical and policy issues in the subject NPRM, which was developed over October 1992 to May 1994 by personnel in your Division of Safety Research (DSR). I am submitting these comments to you as a professional member of your staff before my retirement on September 1, 1994.

The nature and technology of industrial respirators prevent users and purchasers from directly assessing the *safety and efficacy* of the NIOSH-approved respirators they wear and purchase. Thus American respirator users and purchasers must trust the scientific competence and integrity implicit in NIOSH certifications. My attached comments detail how NIOSH's competence and integrity have been grievously compromised.

Three years ago, Dr. Walter Dowdle, Deputy Director, CDC, cautioned NIOSH as follows:

> The integrity of the institution—the reputation of the institution—cannot be taken lightly. To maintain it requires work—every hour in the day, regardless of how many years it has taken to build. One mistake, one scandal, no matter the magnitude of the incident, can hurt and hurt deeply.

> Any negative publicity has serious implications for our ability to carry out our mission "to prevent unnecessary disease, disability, and premature death." And indeed, our ability to carry out our mission depends upon the integrity of the institution being built by all of our employees—no matter what the job. For any outside contact you are CDC. You are the institution's integrity. . . .
>
> Integrity is crucial to our mission. Our success is based on trust.[1]

As Director of NIOSH, your regulatory and watchdog responsibilities for respirators are a higher duty and hold more public trust than those held by the Commissioner of the Food and Drug Administration (FDA) for medical devices. About 7 to 10 million American workers use NIOSH-certified respirators at some time to protect their lives and health. Most workers must wear their NIOSH-certified respirators as an involuntary condition of employment. They have no choice but to put their trust in NIOSH-certified respirators to protect themselves against toxic and lethal workplace conditions.

You must take urgent remedial action to protect millions of American respirator users by rectifying past errors committed by DSR personnel and NIOSH management. In particular, urgent action is needed on my following major recommendations:

- NIOSH should immediately annul and revoke Federal approval certifications for the 3M 9970 HEPA mask.

- NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all NIOSH certifications issued for particulate-filtering respirators.

- NIOSH should immediately withdraw DSR's NPRM of May 1994.

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[1]Dowdle, WR. *Science, Politics, and CDC.* Speech given at the 1991 Alice Hamilton Science Award Symposium on Horizons in Occupational Science at NIOSH, Cincinnati, OH (February 27, 1991) and published in *Current Contents* (October 14, 1991); 41:7-11, page 10.

- NIOSH should terminate all current Federal certifications for respirators and withdraw from its regulatory role as a "watchdog" agency, if the Institute is not ready, willing, or able to provide FDA-style testing and enforcement to protect American respirator users and purchasers.

Nelson A. Leidel, Sc.D.

Enclosures: (1) Comments on 5/94 NPRM (75 pages)
(2) NIOSH's 1992 NPRM Policy for Federal certification of Industrial Respirators (748 pages)

# Comments

# on NIOSH's Second Notice of Proposed Rulemaking

# on Respiratory Protective Devices—42 CFR Part 84

Nelson A. Leidel, Sc.D.
Senior Science Advisor
Office of the Director, NIOSH

August 8, 1994
Atlanta, Georgia

## CONTENTS

## INTRODUCTION

These comments are based on almost 20 years of professional experience in the specialized area of personal respiratory protection programs.[1,2,3,4,5,6,7,8,9,10,11] Additionally, I was NIOSH program manager for the second NPRM for 42 CFR Part 84 over the 5-year period of September 1987 until October 1992. The attachments were developed in the course of my official duties. Several of them constituted Institute and CDC policy at the time they were written. For the last 12 years I have held the position of Senior Science Advisor to the Institute Director, National Institute for Occupational Safety and Health. I have submitted these comments in an effort to protect several million of respirator wearers from the hidden hazards of dust/mist (DM), dust/fume/mist (DFM), and high-efficiency particulate (HEPA) filter respirators.

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[1]Leidel, NA: *Respirator Decision Logic—Joint NIOSH/OSHA Standards Completion Program*. Appendix F in *A Guide to Industrial Respiratory Protection*, NIOSH Technical Report #76–189 (June 1976).

[2]Leidel, NA: *Performance of Faceseal Fit Tests for Respiratory Protection Programs*. Doctoral dissertation, Harvard School of Public Health, Boston, Massachusetts (September 1979).

[3]Leidel, NA: *Requirements for Respirator Fit Testing in the OSHA Lead Standard*. NIOSH Report to the Occupational Safety and Health Administration for Docket H–049A (October 1981).

[4]Leidel, NA: *Supplemental Report to OSHA for Docket H–049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users*. NIOSH Report to the Occupational Safety and Health Administration (October 1982).

[5]Myers, WR, NJ Bollinger, TK Hodous, NA Leidel, SH Rabinovitz, and LD Reed: *NIOSH Respirator Decision Logic*, NIOSH publication #87–108, Cincinnati, Ohio (May 1987).

[6]Leidel, NA: Upgrading NIOSH's Respirator Approval Requirements—A Public Health Necessity, *Applied Industrial Hygiene* 3:F–22 (1988).

[7]Leidel, NA: *Preliminary Regulatory Impact Analysis—42 CFR Part 84, Second Notice of Proposed Rulemaking—Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (September 1989).

[8]Leidel, NA and RJ Mullan: *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis*. NIOSH, Atlanta, Georgia (September 14, 1992).

[9]Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992).

[10]Leidel, NA: *A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists*. NIOSH, Atlanta, Georgia (September 15, 1992).

[11]Leidel, NA. *Analysis of Workplace Particle-Size Information Sent to the NIOSH/OD in June 1993*. NIOSH, Atlanta, Georgia (August 20, 1993).

SPECIFIC RECOMMENDATIONS

- **NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all NIOSH certifications issued for particulate-filtering respirators certified under Subpart K—Dust, Fume, and Mist Respirators (30 CFR 11.130 through 11.140-12).**

  —This independent panel should investigate all DSR and NIOSH correspondence and certification test documentation over at least the last 15 years dealing with all aspects of NIOSH testing, certification, and field performance of DM, DFM, and HEPA particulate respirators.

  —A complete report should be issued by the independent panel regarding any apparent or confirmed irregularities; misconduct; administrative or technical decisions; or any testing criteria that contradict, compromise, or diminish in any way the protection to American respirator users that is implicit in the explicit certification-approval regulatory requirements in 30 CFR Part 11. Remedial, corrective,[12] and disciplinary[13] action should be taken, as appropriate and warranted.

- **NIOSH should immediately annul and revoke Federal approval certifications for the 3M 9970 HEPA mask (TC-21C-437 and OUS TC-21C-438).**

  —NIOSH should publish notification of this revocation in CDC's *MMWR—Morbidity and Mortality Weekly Report*.

  —NIOSH should send out a Respirator User Notice concerning this revocation to the respirator user and purchaser community.

  —NIOSH should require the 3M Company to send letters to all affected purchasers of its 9970 mask notifying them of the revocation of its NIOSH certification.

[12] 5 CFR 2635.102(e).

[13] 5 CFR 2635.102(g).

- **NIOSH should investigate the validity of the UVEX HEPA disposable (NIOSH Approval #TC-21C-604).**

  —NIOSH should determine if this mask was tested and approved by DSR personnel using the same five series of performance tests required of the 3M 9970 in mid-1987.

  —In any case, NIOSH must retest the UVEX HEPA mask to the same 5 series of tests used for 3M's 9970 using proper performance criteria as discussed in Appendix A (page 46).

- **NIOSH should immediately withdraw DSR's NPRM of May 1994.**

  —NIOSH should then promptly propose a third NPRM based on its August 1992 NPRM policy. This third NPRM should be completely candid and honest with regard to the hidden hazards and limitations of current DM- and DFM-filtering respirators.

  NIOSH should fully explain the nature and substance of its pre-NPRM secret ex parte meetings with the regulated respiratory industry. NIOSH should immediately place complete records of all ex parte contacts in the rulemaking record for examination and rebuttal by interested persons.

  —NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all persons in NIOSH and CDC that participated in all ex parte contacts, activities and secret meetings with the regulated respirator industry before the DSR NPRM of May 1994. Remedial action, corrective action,[14] and disciplinary action[15] should be taken, as appropriate and warranted.

  —NIOSH should explicitly reject the protection-delaying, piecemeal approach to regulatory reform that is called the "modular approach" by DSR.

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[14] 5 CFR 2635.102(e).

[15] 5 CFR 2635.102(g).

- **NIOSH should terminate all current Federal certifications for respirators and withdraw from its regulatory role as the "watchdog" agency for 7 to 10 million American respirator users, if it is not able or willing to drastically improve the program's management and regulatory reform activities.**

## RATIONALE FOR RECOMMENDATIONS

- **NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all NIOSH certifications issued by DSR personnel for particulate-filtering respirators certified under Subpart K—Dust, Fume, and Mist Respirators (30 CFR 11.130 through 11.140-12).**

For the reasons given below in extensive discussions presented on pages 5 through 22, there is 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—Dust, Fume, and Mist Respirators (30 CFR 11.130 through 11.140-12). Millions of American users of NIOSH-approved dust masks have been put at risk of sickness and death due to failure of DSR personnel to properly conduct approval tests and due to concealment by DSR personnel of hidden hazards in Federally-approved respirators. There is sufficient evidence to indicate that all existing certifications for Subpart K respirators must be investigated.

The independent outside panel should examine all DSR and NIOSH correspondence and certification test documentation over at least the last 15 years dealing with all aspects of NIOSH testing, certification, and field performance of DM, DFM, and HEPA particulate respirators. A complete report should be issued by the independent panel regarding any apparent or confirmed irregularities; misconduct; administrative or technical decisions; or any testing criteria that contradict, compromise, or diminish in any way the protection to American respirator users that is implicit in the explicit certification-approval regulatory requirements in 30 CFR Part 11. Remedial action, corrective action,[16] and disciplinary action should be taken, as appropriate and warranted.[17,18]

The creation of an independent outside panel that is free of all NIOSH and CDC influence for this investigation is clearly indicated because there are too many officers, civil servants, and managers at NIOSH and CDC that have vested personal interests in the

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[16]5 CFR 2635.102(e).

[17]5 CFR 2635.102(g).

[18]Dahlman, S. *Standards of Conduct*. Memorandum from RADM Suzanne Dahlman, Director, Division of Commissioned Personnel to Active-Duty Commissioned Officers of the U.S. Public Health Service, (July 12, 1994), page 6.

issue of NIOSH certification testing for particulate respirators. What is a stake here is the institutional, scientific, and public health integrity of NIOSH and CDC.

**DSR personnel have committed major procedural errors over a 22-year period in conducting certification testing of DM-filter masks.**

The fundamental purpose of NIOSH testing under 30 CFR Part 11 is to establish and assure respirator users and purchasers of the effectiveness and safety of any NIOSH-certified respirator. Millions of American users of NIOSH-approved dust masks were irresponsibly put at risk of sickness or death from occupational diseases over the 22-year period from 1972 to the present due to the commission of major procedural errors by DSR personnel.

A provision in NIOSH's 30 CFR Part 11 (§ 11.140, Table 9) certification regulations requires that any NIOSH-approved dust and mist (DM) filter mask must have passed a "pressure tightness test." This is one of the tests prescribed for "performance and protection." However, unlike five other performance tests prescribed in Tables 9 and 10 of § 11.140, Part 11 is totally devoid of any description of how to perform the "pressure tightness test." No requirements are given for either the number of respirators or number of test subjects.

This matter was discussed with DSR personnel in July 1992. It was revealed that NIOSH has, since at least the mid-1970s and probably since 1972, "performed a pressure tightness test" using only three masks on one person—the DSR test technician. I evaluated this issue and sent a report to DSR on July 31, 1992. Refer to Appendix C (page 61) of these comments for the full text of this report.

I concluded that DSR personnel had made major procedural errors in their conduct of this test during certification testing for the last 20+ years. These included, but are not limited to:

- DSR personnel should have been performing the test over the last 20+ years according to the requirements of the previous 30 CFR 14.30(a) requirement as follows (ca. late 1960s):

  *Pressure-tightness test (applicable to all respirators designed for respiratory protection against dust, fumes, and mists).* The complete respirator shall be fitted to the faces of 15 to 20

> persons having a wide variety of facial shapes and sizes. To test the suitability of the fit of the respirator on these test subjects, the exhalation valve and the inhalation port(s) shall be held closed, and each subject shall exhale gently into the facepiece until a slight but definite positive pressure is built up in the facepiece. The absence of outward air leakage of air between the facepiece and the subject's face shall be evidence of acceptable fit of the facepiece.

- DSR personnel have committed certification procedural errors by performing the test on only on one person—not the 15 to 20 persons required by Bureau of Mines' regulations for certification testing prior to 1972.[19]

- DSR have apparently failed to perform the test as it was specified in Bureau of Mines' requirements for certification testing before Federal responsibility for testing and approval was transferred to NIOSH in 1972.

- DSR personnel have not performed this test and evaluated the test results for the purpose stated by BuMines regulations, which was to "test the suitability of the fit of the respirator" on the faces "of 15 to 20 persons having a wide variety of facial shapes and sizes" (i.e., a anthropometric fit test panel).

- DSR personnel did not have a written protocol for this test.

Additionally, another danger exists for users of NIOSH-approved dust masks. It appears that over almost 20 years NIOSH has issued certifications to respirators on which a pressure tightness test could not be performed. That is, NIOSH had knowingly certified masks that could not be fit checked as required by OSHA regulations.[20] It is likely that NIOSH did not require any warning to a user that the mask could not meet Federal respirator-use requirements. The NIOSH rationale used for this "exemption" is a regulatory loophole that requires the test only "when applicable."

I strongly recommended to DSR personnel that NIOSH promptly issue both Manufacturers' and Users' Notices stating that NIOSH will no longer perform the pressure tightness test on any respirator submitted for certification since the requirement is **unenforceably vague.** I also recommended that NIOSH notify manufacturers, purchasers, and users of the following:

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[19]Department of Interior regulations 30 CFR 14.30(a), circa late 1960s.

[20]29 CFR 1910.134(e)(5)(i).

- NIOSH's past performance of this test (and requirements that fit check instructions be included with each mask) are immediately voided.

- Manufacturers, purchasers, and users must recognize that a NIOSH approval number means that NIOSH has not evaluated nor approved any fit check test recommended by manufacturers.

- Manufacturers shall include a notice in all User Instructions that NIOSH has not evaluated nor approved any fit check test recommended in the instructions.

Details of my 1992 specific recommendations to DSR personnel are contained in Appendix D (page 66) of these comments. During the exchange of verbal discussions and written recommendations between DSR personnel and myself in mid-1992, they expressed repeated reservations about sending out either a manufacturers' requirement or a User Notice to warn purchasers and users. DSR personnel were reluctant to deal with this issue at all.

It appears that nothing was ever done by DSR personnel to warn users of NIOSH-certified masks concerning this issue. No Users' Notice appears in a December 1993 publication from DSR, which contained a compendium of Users' Notices issued by NIOSH since January 1, 1992.[21]

Any reasonable person would judge the following DSR actions as irresponsible:

(1) Erroneous and invalid performance and evaluation of the 30 CFR 11.140, Table 9 regulatory test requirement for over 22 years, and

(2) Subsequent failure to correct the 22-year-old situation and appropriately warn respirator users and purchasers of potential hidden hazards with their NIOSH-approved masks,

These actions have effectively defrauded American dust-mask users of appropriate respiratory protection. This test is used to certify masks that are currently worn by several million American workers each year.

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[21]NIOSH. *NIOSH Certified Equipment List as of September 30, 1993.* DHHS (NIOSH) Publication No. 94-104 (December 1993), page 26.

DSR's incorrect and invalid testing for the § 11.140, Table 9 requirement, and DSR's subsequent failure to correct the situation and appropriately warn respirator users and purchasers, have needlessly compromised and diminished respiratory protection afforded dust-mask users. A reasonable person would conclude that DSR personnel and management were negligent in this matter because it appears that there was a failure to exercise due care and professional diligence appropriate for NIOSH's approval process and public health responsibilities. There is the appearance of a failure to exercise that degree of care and professional skill rendered appropriate by the particular circumstances of NIOSH's certification and public health responsibilities, and which a person of ordinary prudence in the same situation with equal experience and knowledge would not have omitted.

**DSR personnel have repeatedly failed to warn respirator users about hidden hazards and deficiencies in NIOSH-approved masks.**

There has been a clear and consistent pattern of DSR personnel failing to warn respirator users and purchasers about hidden hazards and deficiencies in NIOSH-approved masks. Millions of American users of NIOSH-approved masks have been put at risk of sickness and death due to concealment by NIOSH of hidden hazards in Federally-approved respirators. DSR personnel have both the public health responsibility and regulatory authority under existing Federal regulations to warn respirator users and purchasers of known or suspected imminent hazards in NIOSH-approved respirators. DSR personnel have repeatedly failed to fulfill their public health responsibilities and exercise their regulatory authority to appropriately and promptly warn respirator users and purchasers of hidden hazards.

For the last 22 years, DSR personnel have had numerous options to warn respirator users and purchasers of recognized or potential hidden hazards in NIOSH-approved masks. Their most accessible communication tool for timely public warnings of hidden hazards in Federally-approved respirators is the NIOSH Respirator Users's Notice.[22] Issuing these Notices require no regulatory approval or authority. Yet these Users' Notices are as rare as hens' teeth.

For over 22 years, DSR personnel have had clear regulatory authority under the existing 30 CFR Part 11 regulation to require manufacturers of NIOSH-approved masks to

[22]NIOSH. *NIOSH Certified Equipment List as of September 30, 1993.* DHHS (NIOSH) Publication No. 94-104 (December 1993), page 26.

adequately warn and fully inform users and purchasers of any suspect or known hidden hazards inherent or present in approved respirators. Specifically, § 11.31(b) requires:

> The certificate of approval shall specifically set forth any restrictions or limitations on the respirator's use in hazardous atmospheres.

Section 11.33(b) authorizes DSR personnel to require approval labels to contain information as follows:

> . . . where appropriate, restrictions or limitations placed upon the use of the respirator by the Bureau and the Institute.

Lastly, § 11.33(c) contains sweeping authority as follows:

> The Bureau shall, where necessary, notify the applicant when additional labels, markings, or instructions will be required.

There have been repeated occurrences of respirator professionals writing to DSR personnel about suspect or potential hidden hazards in NIOSH-approved masks. These include numerous letters from respirator specialists such as Mr. Darell A. Bevis,[23] Mr. John P. Hale,[24] and Mr. Trent Niemeyer.[25]

A typical example of hidden-hazards communications to DSR personnel is given by correspondence from respirator consultant Mr. Darell Bevis. This example is a useful case study in the approach DSR personnel use in discharging their duties as a Federal regulatory agency charged with protecting America's respirator wearers. A letter from Mr. Bevis in October 1993 stated in part to DSR personnel with regard to the 3M 9970 HEPA mask and 2040 HEPA filters:

> I have recently received several inquiries from clients and former students concerning the adequacy of protection provided by two NIOSH/MSHA approved respirators equipped with high-efficiency particulate air (HEPA) filters. The inquiries stem from observations after users in dusty environments that indicated the filters allowed penetration of some of the collected airborne particulate. Both of the approved filters are manufactured by the Minnesota

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[23]Bevis Associates International, Inc., 14640 Flint Lee Rd, Suite D, Chantilly, VA 22021, (703 378-0333.

[24]Respirator Support Services, 2028 Virts Lane, Jefferson, MD 21755, (301) 834-6008.

[25]Filcon Corporation, 1186 St. Clair, St. Paul, MN 55105, (612) 698-9661.

> Mining and Manufacturing (MMM) Company, both are made from a material described by MMM as a permanently charged with "electret" filter media. The approved respirators in question are approval number TC-21C-437 [3M 9970 HEPA[26]] which consists of a disposable type facepiece model from the filter media, and approval number TC-21C-488 [3M 2040 HEPA approved for asbestos[27]] which uses two disk type "electret' filters attached to a facepiece by a retainer without a protective enclosure. . . .
>
> During my research on this potential problem, I discovered that Mr. Charles Coffey of your staff has conducted DOP penetration tests on the two "electret" filters in question. . . . Considering all of the above, Mr. Coffey's test results on the "electret" filters are extremely disturbing since HEPA filters are considered the ultimate respirator filter and are used for protection against exposure to highly toxic particulates or potential carcinogens.[28]

DSR personnel replied in November 1993 to Mr. Bevis as follows in part:

> The 10-second dioctyl phthalate test does not provide a sufficient evaluation of "electret" type HEPA filters, since filter loading is not considered. . . .
>
> The Institute is required to approve and certify respirators that meet the requirements contained in Title 30, Code of Federal Regulations, Part 11 (30 CFR 11). Both TC-21C-437 and TC-21C-488 were approved because they met those requirements, they must continue their approval. . . .
>
> The inadequacies of the filter performance tests in the present certification regulations have long been a concern of NIOSH. . . . The Institute is committed to pursuing a course of action that will rectify this situation in the most expeditious manner possible. At the present time, NIOSH believes that the revisions can be implemented in a timely manner, which will provide a permanent solution to the problem you identify in your letter.[29]

DSR personnel stated that the "inadequacies of the filter performance tests in the present certification regulations have long been a concern of NIOSH." This is a bit of an understatement and appears gratuitous, since DSR have known about the dangerous

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[26]3M Company. *3M Occupational Health & Environmental Safety Division*, 3M pamphlet 70-0703-1377-3 (705) JR, St. Paul, MN (July 1990), page 8.

[27]Ibid., page 9.

[28]Bevis, DA. Letter to Mr. Richard Metzler, Chief, Certification and Quality Assurance Branch, Division of Safety Research, NIOSH, (October 21, 1993), pp. 1-2.

[29]Metzler, RW. Letter to Mr. Darell Bevis, Bevis Associates International, Inc. from Mr. R. W. Metzler (November 23, 1993), pp. 1-2.

deficiencies in numerous Federal approval-test procedures in 30 CFR Part 11 for over 20 years.

The hidden hazard of filter-media deterioration in 3M 9970 masks has serious public health implications for tens of thousands of health-care workers exposed to airborne TB bacilli in their workplace. In the summer of 1992, two panels of DSR personnel repeatedly recommended the 3M 9970 HEPA mask to NIOSH's director as their consensus choice for protection of health-care workers against TB transmission. However, the DSR staff recommendations were rejected when the Institute director made a scientifically sound decision in August 1992 to recommend PAPRs for the scientific reasons extensively summarized in the 1992 NIOSH recommendations.[30]

Then, in late 1993, the 3M 9970 HEPA mask was the primary respirator given the implicit approval, recommendation, and de facto endorsement by NIOSH and CDC for protection of health care workers against TB bacilli in CDC's 1993 draft revision of its 1990 guidelines for tuberculosis prevention in health facilities.[31,32] In consort with CDC about the same time, the Federal Occupational and Health Administration (OSHA) also gave the 3M 9970 HEPA mask its implicit approval, recommendation, and de facto endorsement in an October 1993 memorandum detailing workplace TB-control requirements.[33]

OSHA's 1993 requirements were for a "NIOSH-approved HEPA particulate respirator." The least expensive way to meet OSHA's respirator requirement for TB protection is a disposable HEPA mask—ergo, the 3M 9970. For all practical purposes (e.g., overwhelming market share), the 3M 9970 is only NIOSH-approved HEPA disposable on the market. Ms. Gina Pugliese, director of infection control for the American Hospital Association stated in early 1994:

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[30]Leidel, NA and RJ Mullan: *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis*. NIOSH, Atlanta, Georgia (September 14, 1992), pp. 16-18 and Table 2, pp. 29-30.

[31]CDC: *Draft Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition; Notice of Comment Period*. Federal Register, October 12, 1993; 52810-52854, page 52821 and Supplement 4—Respiratory Protection, pp. 52843-52847.

[32]CDC: *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, With Special Focus on HIV-Related Issues*. MMWR 1990;39(No. RR-17).

[33]Clark, RA. *Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis*. Memorandum from OSHA Directorate of Compliance Programs to OSHA Regional Administrators, October 8, 1993; page 7 and Attachment B, pp. B-1 to B-5.

> To our knowledge, there are only two companies that manufacture disposable HEPA respirators—3M Health Care and UVEX Safety, Inc.[34]

The hidden hazard of the 3M 9970's filter media puts health-care workers at particular risk, because OSHA gave hospitals its approval and de facto endorsement and recommendation to save money by having their employees repeatedly reuse their "disposable" 3M 9970s when it stated in late 1993:

> If a facility chooses to use disposable [HEPA] respirators as part of their respiratory protection program, their reuse is permitted as long as the respirator maintains its structural and functional integrity.[35]

OSHA also reassured 9970 users and purchasers with the comforting words:

> . . . every HEPA filter must be verified by the manufacturer for meeting the di-ethylhexyl phthalate (DOP) penetration requirement described below [less than 0.03% leakage].[36]

However, this reassurance is worthless and potentially misleading to users and purchasers. There is no practical way for hospitals or 9970 users to detect if the filter-media of any given 9970 has deteriorated during use in the workplace and lost its effectiveness or "functional integrity." A 3M 9970 rendered ineffective due to deteriorated filter media cannot be detected by either users or employers or an OSHA compliance officer.

This specific example clearly indicates that DSR personnel have been aware for almost the last 12 months of the hidden hazard of HEPA-filter media deterioration in two models of widely-sold, NIOSH-approved respirators. Results from tests conducted by DSR personnel were available to DSR management long before they received the October 1993 inquiry from Mr. Bevis.

As the Federal "watchdog" agency for respirators, what were the aggressive public health responses by DSR personnel to promptly protect respirator users and purchasers of 3M's

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[34]Weisman, E. *Engineering controls and TB: What works and how well?* Health Facilities Management, February 1994; 18-24, p. 20.

[35]Clark, RA. *Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis*. Memorandum from OSHA Directorate of Compliance Programs to OSHA Regional Administrators (October 8, 1993), page 7.

[36]Ibid., pp. B-3 and B-4.

9970 HEPA disposable masks and 2040 HEPA filters? The latter filters are widely used for half masks, full-face masks, and airline combination systems.

- Did DSR personnel promptly issue a warning about the 3M 9970's hidden hazard to CDC, since the 3M 9970 disposable is the primary HEPA mask that was given the implicit approval, recommendation, and de facto endorsement by NIOSH and CDC for protection of health care workers against airborne TB bacilli?

  No, they did not.

- Did DSR personnel promptly issue a warning about the 3M 9970's hidden hazard to OSHA, since the 3M 9970 disposable is the primary HEPA mask that was given the implicit approval, recommendation, and de facto endorsement by OSHA for protection of health care workers against airborne TB bacilli even after repeated reuse of this "disposable" mask?

  No, they did not.

- Did DSR personnel promptly issue a warning about the 3M 9970's hidden hazard to health-care workers, their unions, the medical community, the American Hospital Association, other affected parties, and appropriate professional journals and newsletters?
  No, they did not.

- Did DSR personnel promptly issue a Respirator Users' Notice to respirator professionals about the hidden hazard of filter-media deterioration?

  No, they did not.

- Did DSR personnel promptly issue a directive to the 3M Company requiring them to: (1) Notify all past purchasers of the 3M 9970 and 2040's hidden hazard and (2) require 3M to immediately place fully informative warnings on all 9970 and 2040 product labels, instructional materials, and sales literature?
  No, they did not.

Instead, DSR personnel stonewalled Mr. Bevis and stated that regulatory reform is the "most expeditious manner" to handle this hidden hazard of filter-media deterioration.

The DSR regulatory changes were proposed in May 1994, which is 7 months after the letter from Mr. Bevis. NIOSH will be lucky if it issues a Final Rule for 42 CFR Part 84 by the end of 1994. DSR's May 1994 regulatory proposal will permit the 3M Company to distribute and sell its 9970s and 2040s as NIOSH approved, with their hidden hazard of filter-media deterioration, for 24 months from the date the new regulation becomes final, which will be the end of 1996 at the absolute earliest.

Bottom line—at least 40 months will elapse between the time that DSR personnel became aware of the 3M 9970's and 2040's hidden hazard in mid-1993 and the earliest date that this respirator and filter cannot be sold as NIOSH-approved. This is what DSR personnel consider "expeditious" protection of American respirator users. DSR personnel have made a conscious decision to permit the 3M Company to continue selling its Federally-certified 9970s and 2040s, with their hidden hazard of filter-media deterioration, without warning American respirator users and purchasers.

Respirator users and purchasers have the *right to know* about any suspect or potential hidden hazards in NIOSH-approved respirators. The Organization Resources Counselors, Inc. (ORC), which is group representing respirator purchasers, have emphatically stated to NIOSH:

> ORC believes that respirator purchasers and users have a "Right To Know"! . . . The right of workers to know the hazards of chemicals they may potentially be exposed to has been firmly established through OSHA's publication of the Hazard Communication Standard, [29 CFR] 1910.1200 and many state regulations. The concept of "Right To Know" has been firmly established in both societal expectations and civil law. There is no logical reason why an individual wearing a respirator in a potentially toxic environment should be in a legally inferior position in regard to the right to know the performance parameters of the respirator he/ she is wearing.[37]

Based on the detailed discussion presented above, any reasonable person would judge the DSR's response to its discover of 3M 9970's filter-media hidden hazard as an irresponsible act that effectively defrauded 9970 and 2040 users and purchasers of the explicit regulatory protection that is supposed to inherent in a Federal certification issued by NIOSH. DSR personnel compromised and diminished user protection specified in

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[37]Organization Resources Counselors, Inc. *Comments on the NIOSH September 15, 1992 Working Draft of "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists."* Transmitted in a January 15, 1993 letter to Dr. Leidel of NIOSH, page 7.

NIOSH regulatory and public health policy requirements. A reasonable person would conclude that DSR personnel and management were negligent in the matter of the hidden hazard in 3M's HEPA-filters because it appears that there was a failure to exercise due care and professional diligence appropriate for NIOSH's regulatory and public health responsibilities.

**DSR personnel made improper and irresponsible NIOSH recommendations to CDC in 1990 regarding the use of "particulate respirators" for health-care worker protection against airborne TB bacilli.**

Scientific recommendations from DSR personnel were the justification for CDC's recommendation in December 1990 for health-care workers to use NIOSH-approved "particulate respirators" (PRs) as adequate worker protection against TB transmission in health-care facilities."[38] Tens of thousands or more of health-care workers were irresponsibly put at risk of sickness or death from TB disease and isoniazid toxicity over the period 1990 to 1993 due to invalid and misleading recommendations from CDC. A CDC official stated in 1994:

> OSHA's [HEPA disposal mask] requirement [of 1993] goes beyond the recommendations contained in the federal Centers for Disease Control and Prevention's (CDC) 1990 TB-control guidelines for health facilities, which do not specify what kind of respiratory protection must be used, says William Jarvis, M.D., chief of the investigations and prevention branch of CDC's hospital infection-control program.[39]

This statement is nonsense. Everyone knew in 1990, or quickly found out, that the cheapest NIOSH-approved "PR" was any model of dust/mist (DM) disposable mask (a.k.a. dust mask). It was well known by DSR personnel that the 3M Company had the lion's share of the respirator market for this type of mask with sales of its 8710 respirator. Thus recommendations from DSR personnel led to the implicit approval, recommendation, and de facto endorsement by NIOSH and CDC of DM disposables, ergo the 3M 8710, for protection against TB bacilli during the period December 1990 and October 1993.

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[38]CDC: *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, With Special Focus on HIV-Related Issues*. MMWR 1990;39(No. RR-17).

[39]Weisman, E. *Engineering controls and TB: What works and how well?* Health Facilities Management, February 1994: 18-24, p. 20.

Most importantly, DSR personnel failed to investigate and consider the following six major technical and public health factors in arriving at their 1990 PR recommendations:

- The existence of severe hazards from tuberculosis infection and clinical disease. DSR personnel failed to investigate and consider in their 1990 PR recommendation the hidden hazard of exposure to isoniazid (INH),[40] which is the mandatory drug of choice for any health-care worker that has been infected with TB.[41] For those on an isoniazid regimen, at least 0.3 to 2.3 per hundred persons develop hepatitis.[42] For almost the last 20 years, the average death rate for those completing an INH regimen is about 1 in 4,200 persons.[43] Additionally, CDC has recognized INH as a confirmed animal carcinogen for over 15 years.[44,45] Under NIOSH policy, INH should be determined to be a *potential human carcinogen* whose occupationally-related exposure should be minimized.

- The existence of severe and excessive leakage that can occur through some models of NIOSH-approved DM disposable masks. DSR personnel were fully aware in 1990 of the excessive leakage through NIOSH-certified DM filters that had been reported to them in the mid-1980s by three different recipients of NIOSH research grants to study respirator filter leakage and by their own researchers.[46]

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[40]Leidel, NA and RJ Mullan: *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis*. NIOSH, Atlanta, Georgia (September 14, 1992), pp. 16-18.

[41]CDC: *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, With Special Focus on HIV-Related Issues*. MMWR 1990;39(No. RR-17).

[42]*Physicians' Desk Reference*.

[43]Snider, DE and GJ Caras. *Isoniazid-Associated Hepatitis Deaths: A Review of Available Information*. Am. Rev. Resp. Dis. 1992; 145:494-497, Table 3, page 495.

[44]Glassroth 1977a: Glassroth, Snider, and Comstock. Urinary tract cancer and isoniazid. Am. Rev. Resp. Dis. 1977; 116:331-333.

[45]Glassroth 1977b: Glassroth, White, and Snider. An assessment of the possible association of isoniazid with human cancer deaths. Am. Rev. Resp. Dis. 1977; 116:1065-1074.

[46]Leidel, NA: *A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists*. NIOSH, Atlanta, Georgia (September 15, 1992), pp. 87-102.

- Knowledge of OSHA's 1986 policy position that disposable respirators "can not be fit checked each time the same or new respirator is donned" and that "as a class, disposable respirators do not provide a reliable face fit after initial fit testing."[47]

- Knowledge of OSHA's determination in the mid-1980s that disposable DM masks must be considered to have at least 20% face-seal leakage because they cannot be reliably fit checked for face-seal effectiveness.[48]

- Knowledge that in 1987, the D.C. Circuit Court of Appeals had upheld OSHA's policy position that disposable DM masks must be considered to have at least 20% face-seal leakage because they cannot be reliably fit checked for face-seal effectiveness.[49]

- The existence of clear warnings in the professional standard of care for respiratory protection programs that both the negative-pressure and positive-pressure fit checks required of respirator users "may be difficult or impossible to carry out on valveless respirators."[50]

Therefore, on the basis of the best available scientific information available to DSR personnel in 1990, any reasonable person would judge the DSR recommendation of DM disposable masks for TB protection as an irresponsible act that effectively defrauded hundreds of thousands of American health-care workers with respect to appropriate respiratory protection over the 3-year period of 1991–1993. DSR's DM disposable recommendation needlessly compromised and diminished health-care worker protection against TB transmission.

A reasonable person would conclude that DSR personnel and management were negligent in their recommended use of DM disposables for health-care workers because it appears that there was a failure to exercise due care and professional diligence appropriate for the hazardous conditions involving recognized exposures to airborne TB bacilli in

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[47]White, FA. Letter from the OSHA Deputy Assistant Secretary to P. G. Nash of Ogletree, Deakins, Nash, Smoak and Stewart. Washington, D.C., September 5, 1986, p. 8.

[48]National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987).

[49]Ibid.

[50]ANSI Z88.2–1980—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1980, § A7.2 and A7.3, pp. 35-36.

health-care facilities. There is the appearance of a failure to exercise that degree of care rendered appropriate by the particular circumstances of CDC's request to NIOSH for a respirator recommendation and NIOSH's public health responsibilities, for which a person of ordinary prudence in the same situation with equal experience and knowledge would not have omitted. There is also the appearance of an unreasonable lack of skill applied in professional duties related to DSR's inappropriate recommendation to use DM disposables.

These preceding three examples of conduct by DSR personnel in the Federal certification of industrial respirators demonstrate the following:

- Major procedural errors during certification testing and approval (page 6)
- Repeated failure to warn respirator users about hidden hazards and deficiencies in NIOSH-approved masks (page 9)
- Improper and irresponsible NIOSH recommendations to CDC in 1990 regarding appropriate protection for health-care workers against airborne TB bacilli (page 16)

These are only three examples of conduct for which I happened to come across without any active attempt to investigate past conduct of DSR personnel. How many cases of similar problems are there?

NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all NIOSH certifications issued by DSR personnel for particulate-filtering respirators certified under Subpart K—Dust, Fume, and Mist Respirators (30 CFR 11.130 through 11.140-12)

- **NIOSH should immediately annul and revoke Federal approval certifications for the 3M 9970 HEPA (i.e., TC-21C-437 and OUS TC-21C-438).**

  —NIOSH should publish notification of this revocation in CDC's *MMWR—Morbidity and Mortality Weekly Report*.

  —NIOSH should send out a Respirator User Notice concerning this revocation to the respirator user and purchaser community.

  —NIOSH should require the 3M Company to send letters to all affected purchasers of its 9970 mask notifying them of the revocation of its NIOSH certification.

The fundamental purpose of NIOSH certification testing of respirators by DSR personnel under the Federal regulatory requirements 30 CFR Part 11 is to establish and assure respirator users and purchasers of the effectiveness and safety of any NIOSH-certified respirator. Tens of thousands of 3M 9970 mask users have been put at risk of sickness and death due to invalid and improper approval by DSR personnel when they issued Federal approval certifications to the 3M Company for its 9970 HEPA mask.

Based on the detailed discussion presented in Appendices A (page 46) and B (page 56), any reasonable person would judge the improper certification of the 3M 9970 by DSR personnel in 1987 as an irresponsible act that effectively defrauded American respirator users and purchasers of the explicit regulatory protection that is supposed to inherent in a Federal certification issued by NIOSH. DSR personnel compromised and diminished user protection specified in NIOSH regulatory and science policy requirements. A reasonable person would conclude that DSR personnel and management were negligent in the invalid approval and certification of the 3M 9970 because it appears that there was a failure to exercise due care and professional diligence appropriate for NIOSH's approval and certification of the 3M 9970.

The invalid approval of the 3M 9970 mask has serious public health implications for tens of thousands of health-care workers exposed to airborne TB bacilli in their workplace. In the summer of 1992, two panels of DSR personnel repeatedly recommended the 3M 9970 HEPA mask to NIOSH's director as their consensus choice for protection of health-care workers against TB transmission. However, the DSR staff recommendations were rejected when the Institute director made a scientifically sound decision in August 1992

to recommend PAPRs for the scientific reasons extensively summarized in the 1992 NIOSH recommendations.[51]

Other public health considerations relevant to revoking the 3M 9970's certification is that this disposable mask is the primary respirator that was given the implicit approval, recommendation, and de facto endorsement by NIOSH and CDC for protection of health care workers against TB bacilli in CDC's 1993 draft revision of its 1990 guidelines for tuberculosis prevention in health facilities.[52,53] Similarly, the Federal Occupational and Health Administration (OSHA) has also given the 3M 9970 HEPA mask its implicit approval, recommendation, and de facto endorsement in late 1993.[54] Refer to the discussion starting on page 12 for the details of these recommendations.

In addition to the 3M 9970's questionable face-seal effectiveness, there is another safety and effectiveness problem associated with the 3M 9970 mask. Refer to the discussion starting on page 10 regarding the hidden hazard of filter-media deterioration affecting 3M 9970s.

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[51]Leidel, NA and RJ Mullan: *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis*. NIOSH, Atlanta, Georgia (September 14, 1992), pp. 16-18 and Table 2, pp. 29-30.

[52]CDC: *Draft Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition; Notice of Comment Period*. Federal Register, October 12, 1993; 52810-52854, page 52821 and Supplement 4—Respiratory Protection, pp. 52843-52847.

[53]CDC: *Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, With Special Focus on HIV-Related Issues*. MMWR 1990;39(No. RR-17).

[54]Clark, RA. *Enforcement Policy and Procedures for Occupational Exposure to Tuberculosis*. Memorandum from OSHA Directorate of Compliance Programs to OSHA Regional Administrators, October 8, 1993; page 7 and Attachment B, pp. B-1 to B-5.

- **NIOSH should investigate the validity of the UVEX HEPA disposable (NIOSH Approval #TC-21C-604)**

  —NIOSH should determine if this mask was tested and approved by DSR personnel using the same five series of performance tests required of the 3M 9970 in mid-1987.

  —In any case, NIOSH must retest the UVEX HEPA mask to the same 5 series of tests used for 3M's 9970 using proper performance criteria as discussed in Appendix A (page 46).

As discussed on the previous page, the UVEX HEPA disposable is one of two HEPA disposables that were given the implicit approval, recommendation, and de facto endorsement by NIOSH, CDC, and OSHA for protection of health care workers against airborne TB bacilli. Since the UVEX approval testing was performed 6 to 7 years after the 1987 approval of the 3M 9970 under the direction of a different DSR branch chief, it is probable that the UVEX mask did not undergo the corn oil testing required of the 3M 9970. If the UVEX was not tested to exactly the same test series and criteria as the 3M 9970, then there arises the serious and troubling issue of NIOSH treating similar certification applications in different ways.

Even if the UVEX HEPA was tested to the same series of tests and performance criteria as the 3M 9970, it must be retested to proper criteria as discussed in Appendix A (page 46) for the isoamyl acetate face-seal effectiveness test and the corn oil face-seal effectiveness test. If this retesting is not performed, NIOSH would be potentially defrauding American respirator UVEX users and purchasers of the explicit regulatory protection that is supposed to inherent in a Federal certification issued by NIOSH. If the UVEX cannot meet the proper performance criteria detailed in Appendix A (page 46) and NIOSH does not perform the retesting, NIOSH would be compromising and diminishing UVEX user protection as specified in NIOSH regulatory and science policy requirements.

- **NIOSH should immediately withdraw DSR's NPRM of May 1994.**

  —NIOSH should then promptly propose a third NPRM based on its August 1992 NPRM policy. This third NPRM should be completely candid and honest with regard to the hidden hazards and protection limitations of current DM-, DFM-, and HEPA-filtering respirators.

  —NIOSH should fully explain the nature and substance of its pre-NPRM secret ex parte meetings with the regulated respiratory industry. NIOSH should immediately place complete records of all ex parte contacts in the rulemaking record for examination and rebuttal by interested persons.

  —NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all persons in NIOSH and CDC that participated in all ex parte contacts, activities and secret meetings with the regulated respirator industry before the DSR NPRM of May 1994. Remedial action, corrective action,[55] and disciplinary action[56] should be taken, as appropriate and warranted.[57]

  —NIOSH should explicitly reject the protection-delaying, piecemeal approach to regulatory reform that is called the "modular approach" by DSR.

**DSR personnel have irreversibly tainted the proposal with ex parte secret meetings with the regulated industry.**

Restrictions on *ex parte* communications—that is, off-the-record communications between interested parties and Federal government staff during informal rulemaking proceedings, such as for 42 CFR Part 84, have been summarized as follows:

> Once a notice of proposed rulemaking has been issued pursuant to the Administrative Procedure Act (5 U.S.C. § 553) there should be no oral communications between interested persons and officials of the agency dealing with the merits of the proposed rules outside the

[55] 5 CFR 2635.102(e).

[56] 5 CFR 2635.102(g).

[57] Dahlman, S. *Standards of Conduct*. Memorandum from RADM Suzanne Dahlman, Director, Division of Commissioned Personnel to Active-Duty Commissioned Officers of the U.S. Public Health Service, (July 12, 1994), page 6.

> confines of public meetings or hearings conducted in accordance with public notices, and no written communications dealing with the merits of the proposed rules that are not placed in the public file or record of the rulemaking proceedings in accordance with established procedures designed to make them available for examination and rebuttal by interested persons.[58]

The rationale for this stringent "fencing off" of Agency personnel from the regulated industry is that ex parte communications are inconsistent with adequate judicial review on the "full administrative record" in accordance with *Citizens to Preserve Overton Park, Inc. v. Volpe*[59] and inconsistent with "fundamental notions of fairness implicit in due process."[60,61] In *Sierra Club v. Costle* the court ruled that certain documents received outside the record—those documents of "central relevance to the rulemaking" as well as those which produce "significant new information"—should be placed in the docket as soon as possible after they became available.[62]

During the decade of the early 1980s through September 1992, NIOSH management maintained a strict "fencing off" policy between NIOSH staff and management and the regulated industry, which was primarily represented by the Industrial Safety Equipment Association, Inc. (ISEA) and the Jefferson Group. For the period 1987-1992, about one meeting annually occurred between Federal officials and the regulated industry. Memoranda to the record were scrupulously prepared for each meeting.

In early 1991, the General Counsel for the Department of Health and Human Services issued the following warning to all DHHS officials:

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[58]Nathanson. *Report to the Select Committee on* Ex Parte *Communications in Informal Rulemaking Proceedings*, 30 AD. L. REV. 377 (1978).

[59]401 U.S. 402 (1971).

[60]*Sangamon Valley Television Corp v. United States*, 269 F.2d 221 (D.C. Cir. 1959).

[61]Nathanson. *Report to the Select Committee on* Ex Parte *Communications in Informal Rulemaking Proceedings*, 30 AD. L. REV. 377 (1978).

[62]657 F.2d 298 (D.C. Cir. 1981).

> . . . Department officials should refrain from meeting with outside groups to discuss the merits or flaws of proposed regulations once rulemaking has begun unless accurate notes of the meeting are taken and inserted in the administrative record.[63]

In early 1994, I learned that DSR personnel had repeatedly met with personnel from the regulated industry (ISEA) over the preceding several months with regard to NPRM regulatory requirements under development by DSR, which were subsequently published in May 1994. I was told by an authoritative source who attended these meetings that the regulated industry was given access to the detailed test methods and test approval criteria for respirator filters for their examination and comment. Respirator purchasers and users were not notified of these ex parte meetings and were not given similar access to the draft DSR requirements.

I subsequently asked an attorney in the CDC's Office of the General Counsel about the propriety of these meetings and if Departmental and CDC policy had changed with regard to the strict prohibition on ex parte meetings. I was told that the issue "was none of my business."

It appears that these unilateral, secret meetings were used by the regulated industry as a back door, unpublicized, direct channel of access to those DSR personnel that were responsible for writing the 2nd NPRM. These meetings provided privileged access of the regulated industry to DSR personnel. The vested interests of the regulated industry include respirator sales of several hundred million dollars each year, which will be affected by the new NPRM requirements.

It is likely that the secret meetings between DSR personnel and the regulated industry involved the transfer of material factual information directly bearing on the specific test procedures and test criteria to be included in the proposed rule for future respirator certification testing. The occurrence of these meetings denies interested parties the opportunity for informed comment and criticism on material discussed or transferred at these meetings.

Additionally, ex parte meetings may violate either the letter or spirit of Federal regulations 5 CFR 2635.101(b)(8) and (b)(14), which state:

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[63]Astrue, MJ. Ex Parte *Communications During Department Rulemaking Proceedings*. Memorandum from Mr. Michael J. Astrue, General Counsel, DHHS to DHHS Heads of Operating Divisions and Heads of Staff Divisions (February 8, 1991), page 2.

> (8) Employees shall act impartially and not give preferential treatment to any private organization or party.
>
> (14) Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in this part. Whether particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts.

What is particularly disturbing about these ex parte meetings with NIOSH is that they give the appearance that DSR staff and NIOSH management believe that their 1994 rulemaking can be conducted in the same cozy fashion with the regulated industry as was done in 1971 for the 22-year-old 30 CFR Part 11. The Preamble for the 1972 Final Rule for 30 CFR Part 11 provides not one iota of technical or public health rationale for the regulations used for the last two decades.[64] The unrecorded and friendly interactions in 1971 between Departmental officials and the regulated industry were documented only to the following extent, since no docket ever existed for the 1971 NPRM:

> In addition interested parties informally conferred with officials of the Department of the Interior and the Department of Health, Education, and Welfare in March, April, October, and November 1971 in order to discuss the proposed amendments [to 303 CFR Part 11].[65]

In 1994, DSR personnel did not even bother to reveal in their Preamble the dates they met with the regulated industry.[66]

NIOSH should immediately withdraw DSR's NPRM of May 1994. NIOSH should immediately place complete and detailed records of all ex parte contacts between any NIOSH personnel and management officials into the rulemaking record for examination and rebuttal by interested persons. NIOSH should request the creation of an independent outside panel that is free of all NIOSH and CDC influence to investigate all persons in NIOSH and CDC that participated in all ex parte contacts, activities and secret meetings with the regulated respirator industry before the DSR NPRM of May 1994. Remedial

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[64]37 FR 6244 (March 25, 1972).

[65]Ibid.

[66]59 CFR 26850 (May 24, 1994), pp. 26850-26857.

action, corrective action,[67] and disciplinary action[68] should be taken, as appropriate and warranted.[69]

**DSR personnel have proposed a regulatory revision that is defective because the proposed rule denies the opportunity for informed comment and criticism.**

The Preamble for the 1994 NPRM provides not one iota of technical or public health rationale for the proposed regulatory reform.[70] The Preamble merely states *what* NIOSH proposes to do. It does not state *why* NIOSH believes these changes are necessary for particulate filters. More importantly, the Preamble fails to state *why* NIOSH believes other changes are indicated as "future modules." If there are hidden hazards and effectiveness limitations with currently-approved respirators, users and purchasers have the right to know about problems now, not years later as DSR proposes to do. Therefore, the regulatory revision is substantively defective because the proposed rule denies interested parties any opportunity for informed comment and criticism. NIOSH should immediately withdraw DSR's NPRM of May 1994.

The *why* for the necessary changes in 30 CFR Part 11 were detailed in the 495-page (588 footnotes) Preamble in NIOSH's 1992 policy for this NPRM.[71] The entire 748-page policy document has been attached to the transmittal memorandum to the Director of NIOSH and should be considered a part of these comments.

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[67]5 CFR 2635.102(e).

[68]5 CFR 2635.102(g).

[69]Dahlman, S. *Standards of Conduct*. Memorandum from RADM Suzanne Dahlman, Director, Division of Commissioned Personnel to Active-Duty Commissioned Officers of the U.S. Public Health Service, (July 12, 1994), page 6.

[70]59 CFR 26850 (May 24, 1994), pp. 26850-26857.

[71]Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992), pp. 1-495.

**DSR personnel have written a Preamble that is erroneous in its conclusions and recommendations for no changes in Assigned Protection Factors (APFs) proposed by NIOSH in 1992.**

The Preamble for the 1994 NPRM states the following with regard to the protection afforded by currently-certified particulate masks:

> NIOSH has long been concerned with the health risks to workers due to the inappropriate selection and use of dust/mist and dust/fume/mist respirators. Assigned Protection Factor (APF) values are used in the respirator selection process to indicate the expected protection level. NIOSH has considered the possibility of reducing the Assigned Protection Factor (APF) values given in the NIOSH Guide to Industrial Respiratory Protection and in the Respirator Decision Logic for dust and fume (sic) respirators to account for filter penetration that can occur, theoretically, when these respirators are inappropriately used against aerosols less than 2 micrometers in diameter. On September 15, 1992, NIOSH prepared (sic) a draft report, "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mist (sic)," explaining its concerns and suggested course of action. NIOSH solicited an external scientific peer review of this draft report on September 15, 1992. This review did not support an immediate revision of the APF values. The reviewers recommended that NIOSH address the concern about excessive filter penetration by incorporating improved filter-penetration tests into the respirator certification regulation.
>
> After careful consideration of the this issue, NIOSH agrees with the scientific reviewers that, during the [2-years or more] transition period for the implementation of the provisions contained in this rule, an adjustment of APF values is unnecessary and may confuse respirator users. NIOSH will continue to recommend the APF values contained in the NIOSH Guide to Respiratory Protection (September 1987) and in the Respirator Decision Logic (May 1987) for respirators previously certified under the provisions of 30 CFR Part 11.[72]

Since I was the author of the September 15, 1992 NIOSH report[73] referenced in the Preamble, I believe I am well qualified to comment on the conclusions and recommendations of DSR personnel regarding the recommendations that I was responsible for. These recommendations constituted both NIOSH and CDC policy in mid-1992. There are numerous omissions and misleading statements in the 1994 presentation by DSR

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[72]59 FR 26850 (May 24, 1994), page 26851-26852.

[73]Leidel, NA: *A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists*. NIOSH, Atlanta, Georgia (September 15, 1992).

personnel that prevent an interested party from making informed comments on the following two principal conclusions in the Preamble:

> (1) The peer review "did not support an immediate revision of the APF values" for currently-approved DM and DFM masks as given in my 1992 evaluation.[74]
>
> (2) The reviewers concluded that an adjustment of APF values is unnecessary and may confuse respirator users.

First, the Preamble failed to stated the numerous findings and recommendations presented in my 1992 evaluation. The findings were summarized in the following public-health bottom line for the evaluation of hidden leakage through DM and DFM filters:

> In summary, after conducting the evaluation discussed in this section of the evaluation [pages 103-113] and based on the best available evidence, NIOSH concludes that contaminant leakage through some widely-used DM and DFM filters currently certified by the Institute can create a hazard for respirator users. Additionally, because of their widespread usage against several hundred toxic contaminants, the excessive leakage exhibited by some DM and DFM filters is a significant public health hazard.[75]

A reader of the NIOSH Preamble is given the erroneous impression that the only solution recommended by NIOSH in 1992 and considered by the peer reviewers was a reduction in APF values. This is not the case. In fact, most of the reviewers comments failed to cover or convincingly rebut the following NIOSH conclusions:

- NIOSH concludes that DM- and DFM-filter mask users can be unknowingly exposed to hazardous contaminants leaking through their filters because they generally have no warning properties.[76]

- NIOSH concludes that smaller contaminant sizes can be more toxicologically potent than indicated by their proportional mass contribution to inhaled doses received by respirator wearers via filter leakage. Unfortunately for respirator wearers, the inhalation of smaller contaminant sizes by filter-mask wearers is expected to occur with the type of

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[74]Ibid., 1992), Table P, page 129.

[75]Ibid., page 113.

[76]Ibid., page 109.

significant leakage known to occur through DM and DFM filters. The same effect occurs with leakage past a respirator's face seal.[77,78,79]

- NIOSH concludes that filter-mask purchasers and users have not been provided with appropriate instructions to permit the safe and effective use of these respirators against all sizes of hazardous contaminants.[80]

- NIOSH concludes that the labels for NIOSH-certified DM- and DFM-filters create an erroneous perception for purchasers and users that these filters will protect against *all sizes* of dusts, fumes, and mists. The clearly implied, but apparently incorrect message to a purchaser or user of NIOSH-certified filters is that they will protect a user from *any size* dry dust or wet mist and *any size* fume generally below 1 $\mu$m diameter.[81]

- NIOSH concludes that contaminant-size information for workplace exposures is not readily available to filter purchasers and users to enable them to make informed decisions as to when to avoid the use of DM or DFM filters. NIOSH also concludes that it is highly doubtful that employers would choose to do additional contaminant-size monitoring because few of them currently do the OSHA-required exposure-level monitoring.[82]

Second, the DSR Preamble statements do not explain the history of my report and the limited context in which it was publicly released on September 15, 1992. My "draft report" was actually a section lifted out of context from a much-larger, 495-page Preamble that was part of the total 748-page regulatory proposal, which was NIOSH and CDC policy in mid-1992.[83] DSR personnel had fully reviewed and fully concurred with the material contained in the full regulatory reform of 1992. The late-1992 "draft report"

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[77]Hinds, W. C. and G. Kraske: Performance of Dust Respirators with Facial Seal Leaks: I. Experimental. *Am. Ind. Hyg. Assoc. J.* 48(10):836–841 (1987).

[78]Holton, P. M. and K. Willeke: The Effect of Aerosol Size Distribution and Measurement Method on Respirator Fit, *Am. Ind. Hyg. Assoc. J.* 48(10): 855–860 (1987).

[79]Leidel, NA: *A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists*. NIOSH, Atlanta, Georgia (September 15, 1992), page 111.

[80]Ibid., page 111.

[81]Ibid., page 112.

[82]Ibid., page 113.

[83]Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992), pp. 1-495.

guise was part of a political compromise that was presented to and agreed upon by the DHHS Assistant Secretary for Health in early September 1992.

The actual objective of the alleged "draft report" was to have the science I had used in my evaluation submitted for public comment. However, NIOSH's proposed regulatory reform intended to solve the danger of hazardous leakage through DM and DFM filters, was not presented to those attending 3 presentations given in Washington, DC on September 15, 1992 by Dr. Richard Lemen, Deputy Director, NIOSH. Likewise, the solutions offered in the proposed regulatory reform were withheld from the 5 reviewers of my report.

Thus, the regulated industry (e.g., ISEA) and several of the reviewers thought that a draconian NIOSH ban of all DM and DFM filter masks was imminent and no other solution was being considered by NIOSH. It was widely thought that NIOSH perceived actions would be result in hundreds of millions in lost sales to respirator manufacturers for several years. Additionally, employers and users would have not have access to disposable masks for several years. I believe that these misperceptions biased the comments from several reviewers.

Third, from the DSR statements in the Preamble, a reader probably would have the impression that the 5 reviewers[84] were unanimous and unequivocal regarding the two principal conclusions stated in the Preamble about revising current APFs for current DM- and DFM-filter masks (see page 29). This is not the case. In fact, the most senior and distinguished of the 5 reviewers, Dr. Morton Lippmann, stated in part:

> With respect to the five explicit issues raised in your letter, I offer the following commentary:
>
> 1. The explicit and implicit assumptions supporting the evaluation: The document identifies the key assumptions and discusses them quite adequately.
>
> 2. The four independent research studies on filter leakage: The four studies were performed by very well qualified and highly respected investigators, and there is no reason to

[84]Dr. Morton Lippmann, NYU Medical Center; Mr. Bill Kojola, Laborers' Health and Safety Fund of North American; Mr. Bruce D. Reinert, Los Alamos National Laboratory; Dr. Clifton D. Crutchfield, University of Arizona Health Sciences Center; and Dr. Lisa M. Brosseau, University of Minnesota School of Public Health.

question either the validity of the data they generated, or the NIOSH staff's treatment and analyses of these data.

3. The criteria by which data were selected from these studies to conduct the evaluation: The document was based upon a reasonable selection and analysis of the data.

4. The formulations and calculations used in the evaluation: These were clearly stated and appropriate.

5. The conclusions of the evaluation: The conclusions in the document are reasonable, sound, and straightforward. They are well justified by the objective data.[85]

In contrast to these definitive, supportive evaluations, the other 4 reviewers were mixed in their negative reactions and opinions. My summary of their views is as follows. I recommend that any interested party obtain the full reviews to draw their own conclusions. DSR staff chose not to place the 5 reviews into the rulemaking docket.

**Kojola:** He stated that "the NIOSH proposal to lower the APF's for DM and DFM masks, based upon the filter leakage studies, is premature and inappropriate." He also said that "the wide variability in filter leakage for DM and DFM filter materials in indicative of a problem that needs to be addressed."[86]

**Reinert:** He did not concur with the conclusions "since I believe that NIOSH has not been completely objective in their evaluation." "I would like to recommend that NIOSH rethink their stand on this issue." "I would prefer to be involved in some discussions with all concerned parties before making up my mind on the best approach. With only the NIOSH and ISEA input available, I would have to vote for not changing any APFs."[87]

**Crutchfield:** "These comments are general in nature, in contrast to the train of specific assumptions and conclusions that are used to arrive at the recommended assigned protection factors listed in Table P of the Draft." "Improving the quality and dissemination

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[85]Lippmann, M. Letter from Dr. Morton Lippmann, NYU Medical Center to Ms. Diane D. Porter, Assistant Director for Legislation and Policy Coordination, NIOSH (January 4, 1993).

[86]Kojola, B. Letter from Mr. Bill Kojola, Laborers' Health and Safety Fund of North America to Ms. Diane D. Porter, Assistant Director for Legislation and Policy Coordination, NIOSH (January 22, 1993), page 8.

[87]Reinert, BD. Letter from Mr. Bruce D. Reinert, Los Alamos National Laboratory to Ms. Diane D. Porter, Assistant Director for Legislation and Policy Coordination, NIOSH (April 8, 1993), page 8.

of respirator selection information may be a better control alternative than essentially banning a class of media that can provide effective protection if it is properly selected and used." "Since PELs are generally mass based, the use of count based penetration data is also questionable." "Could not the NIOSH certification process screen out the big-time DM leakers, so that the more difficult to control issue of faceseal leakage remains the major concern of employers, workers, and occupational health professionals?"[88]

**Brosseau:** She recommended that "changes in the certification tests outlined in the 1987 version of 42 CFR 84 be adopted by NIOSH as a means of controlling any "unacceptable" filter penetration, and that NIOSH address the process of filter selection on the basis of these new certification tests." "There will be no need to lower the APFs on the basis of filter behavior with these changes." "Given the above [8] points, the evidence is not strong enough to support the lowering of the APFs on the basis of facepiece leakage."[89]

My conclusion is that taken as a whole, the reviewers conclusions were far from the consensus implied in the Preamble statements. My summary is that one reviewer definitively agreed with the 1992 document (Lippmann), one did not present a definitive recommendation one way or another (Crutchfield), and three did not concur with the 1992 document (Kojola, Reinert, and Brosseau).

Scientific inquiry and peer review is not necessarily a democracy with "one person, one vote." If one properly takes into account Dr. Lippmann's professional seniority, unique technical expertise in the subjects covered by the report, and professional experience in advising government agencies, I will argue that the conclusions from the 5 reviewers, when taken as a whole, are conflicting and equivocal. I was unable to find a statement from these reviewers that an adjustment of current APF values "may confuse respirator users." Therefore, the two principal DSR Preamble conclusions (see page 29) are at best misleading and at worse they are fraudulent and possibly represent scientific misconduct.

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[88]Crutchfield, CD. Letter from Dr. Clifton D. Crutchfield, University of Arizona Health Sciences Center to Ms. Diane D. Porter, Assistant Director for Legislation and Policy Coordination, NIOSH (February 5, 1993).

[89]Brosseau, LM. Letter from Dr. Lisa M. Brosseau, University of Minnesota School of Public Health to Ms. Diane D. Porter, Assistant Director for Legislation and Policy Coordination, NIOSH (January 15, 1993).

Fourth, none of the reviewers dealt directly with the pressing problem of NIOSH's public-health duty and responsibility to protect users and purchasers of current DM and DFM masks during the long rulemaking process and the 2-year or longer "grandfathering" or "phase-out" period for inventories of filters with the hidden hazard of excessive filter leakage. DSR's Preamble similarly neglects to deal with this hazard that continues to threaten respirator users and purchasers.

The four DM- and DFM-filter-leakage studies reported in my 1992 Preamble and "draft report" were given to DSR personnel in the late 1980s. DM-filter masks are widely used by several million Americans each year. As the Federal "watchdog" agency for respirators, what were the aggressive public health responses by DSR personnel between the late 1980s and 1994 to promptly protect respirator users and purchasers from the hidden hazards of DM-filter leakage?

- Did DSR personnel promptly issue a Respirator Users' Notice warning respirator professionals about the significant hidden hazard of leakage through certain DM-filter masks?

  No, they did not.

- Did DSR personnel promptly issue a warning about the significant hidden hazard of leakage through certain DM-filter masks to respirator users, purchasers, other workers, their unions, other affected parties, and appropriate professional journals and newsletters?

  No, they did not.

- Did DSR personnel promptly issue a directive to manufacturers of DM-filter masks requiring them to: (1) Notify all past purchasers of their masks with a warning about the significant hidden hazard of leakage through certain DM-filter masks and (2) require the manufacturers to immediately place fully informative warnings on their product labels, instructional materials, and sales literature?

  No, they did not.

Fifth, and last, DSR failed to report or discuss significant results reported in a 19-page analysis performed at the request of the Acting Director for NIOSH.[90] The report's findings refute several of the key criticisms contained in comments by the ISEA and the 5 peer reviewers of my 1992 evaluation of DM- and DFM-filter leakage hazards.[91] The transmittal memorandum for the report is given as Appendix E (page 72) to these comments. The report was peer reviewed in NIOSH by over half a dozen persons. There were no negative comments received and the positive reports concurred with the importance and validity of the recommendations. DSR personnel failed to submit any review comments, even though three of DSR's management officials had received copies of the report.

My most important conclusions included these three[92]:

> In a wide range of workplaces and operations, workers are exposed to particle sizes under 3 $\mu$m AED (aerodynamic equivalent diameter) and particle mass distributions with <2-$\mu$m MMADs (mass median aerodynamic diameter.[93] Worker exposures to these "smaller particles" is not just a theoretical possibility.
>
> NIOSH does have ample data indicating that numerous workplaces contain aerosols with a substantial fraction of their total mass in the 0.2- to 3.0-$\mu$m AED size range. For a wide range of workplaces and operations, a mass leakage model I developed predicts substantial mass leakage through DM filters currently approved and marketed under the requirements of 30 CFR Part 11. For example, estimated filter leakage ranges from 3.5% to 26.1% mass leakage through the Gerson 1710 mask at 50 Lpm (refer to Figure 5 attached to the short report).
>
> Respirator manufacturers were incorrect when they stated at the June 15, 1993 meeting with NIOSH that adequate worker protection is created if employers use the ANSI criterion of <2 $\mu$m MMAD for requiring workplace use of HEPA filters. They stated that the total mass leakage through currently-certified DM filters is irrelevant for workplace with MMADs over 2 $\mu$m. These statements are contradicted by Figures 4 and 5 attached to my analysis.

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[90]Leidel, NA. *Analysis of Workplace Particle-Size Information Sent to the NIOSH/OD in June 1993.* NIOSH, Atlanta, Georgia (August 20, 1993).

[91]Leidel, NA: *A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists.* NIOSH, Atlanta, Georgia (September 15, 1992).

[92]Appendix E, pp. 1-2.

[93]For an aerosol with a mass median aerodynamic diameter of 2 $\mu$m, 50% of the total mass is contributed by particles with aerodynamic equivalent diameters less than 2 $\mu$m.

The results and conclusions in my August 1993 analysis corroborate the findings in my 1992 DM- and DFM-filter-leakage evaluation. In particular, the 1993 analysis supports the 1992 bottom line that:

- Contaminant leakage through some widely-used DM and DFM filters currently certified by the Institute can create a hazard for respirator users.

- The excessive leakage exhibited by some DM filters is a significant public health hazard.

Based on the preceding five issues, any reasonable person would judge the 1994 Preamble statements and conclusions that APF revisions are unnecessary as irresponsible acts, which have effectively defrauded American respirator users and purchasers of the inherent protection in current Federal certifications issued by NIOSH for DM- and DFM-filter masks. The statements by DSR personnel, when combined with their failure to warn DM-mask users and purchasers of the hidden hazard of excessive DM-filter leakage, have compromised and diminished user protection specified in NIOSH regulatory and science policy requirements. A reasonable person would conclude that DSR personnel and management were negligent in their Preamble statements and conclusions that APF revisions are unnecessary. It appears that there was a failure to exercise due care and professional diligence appropriate for NIOSH's public health duties and responsibilities to respirator users and purchasers.

For these reasons, NIOSH should immediately withdraw DSR's NPRM of May 1994. NIOSH should immediately place in the rulemaking record at least the following: (1) the 1992 evaluation of hazardous DM and DFM filter leakage, (2) the five peer reviews for that 1992 evaluation, (3) the 19-page analysis of August 20, 1993 regarding workplace particle-size information, and (4) all NIOSH peer reviews for that 1993 analysis.

Additionally, NIOSH should:

- Promptly issue a Respirator Users' Notice warning respirator professionals about the significant hidden hazard of leakage through certain DM-filter masks.

- Promptly issue a warning about the significant hidden hazard of leakage through certain DM-filter masks to respirator users, purchasers, other workers, their

unions, other affected parties, and appropriate professional journals and newsletters.

- Promptly issue a directive to manufacturers of DM-filter masks requiring them to:

  — Notify all past purchasers of their masks with a warning about the significant hidden hazard of leakage through certain DM-filter masks, and

  — Require respirator manufacturers to immediately place fully informative warnings on their product labels, instructional materials, and sales literature.

**DSR personnel have proposed continued use of invalid test methods for evaluating the hidden hazard of face-seal leakage.**

One of the most dangerous omissions from the DSR NPRM is the total lack of any discussion concerning the hidden hazard of face-seal leakage. What is worse, DSR has proposed to continue the use of invalid test methods for evaluating face-seal effectiveness during approval testing. NIOSH policy of August 1992 stated the following about current NIOSH certifications[94]:

> None of the current certifications are based on valid testing for face seal protection. A respirator face seal is one of the most critical components affecting safety and protection provided by any respirator. When performed, the current testing of this component with qualitative fit tests[95] may be unreliable for detecting unsafe or ineffective face seals. This area will be addressed with the requirements of Subpart R [Face-Seal Leakage]. . . .
>
> The function of Subpart R is to set forth the minimum performance requirements for face-seal protection of negative-pressure respirators. The testing required in this Subpart and face-seal performance criteria proposed in Table 3 for § 84.232(h) are essential to provide assurance that each negative-pressure, NIOSH-certified respirator has adequate face-seal capability for a wide range of facial sizes and shapes. Currently, most NIOSH-certified respirators have not been validly tested where it really counts—on human faces.

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[94]Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992), pp. 14-15 and 391-392.

[95]Isoamyl acetate used at 100 ppm or 1,000 ppm (i.e., 30 CFR §§ 11.85–19, 11.102–3(e), 11.140, 11.162–3(e), and 11.183–3(e)); number of test subjects not specified except for SCBA devices.

> 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. In particular, prospective wearers with small facial sizes (e.g., women, Hispanics, Asians) should have a reasonably large probability of receiving APF-level protection with a NIOSH-certified respirator when the device is correctly worn. This is particularly important because between the years 1990 to 2000, 88% of American work-force growth will come from women, blacks, and people of Hispanic or Asian origin, including immigrants.[96]

Most importantly, NIOSH policy stated in 1992:

> For negative-pressure, air-purifying respirators and non-powered atmosphere-supplying respirators, the ability of the facepiece to seal with the wearer's face is the functional aspect that typically limits the protection provided to respirator wearers. Therefore, the Institute considers it essential that NIOSH-certified respirators demonstrate adequate face-seal fitting abilities in, at a minimum, laboratory tests. This is because currently available quantitative and qualitative fits tests have not been satisfactorily demonstrated to be capable of effectively identifying (screening out) those wearers with inadequately-fitting respirators. Additionally, this testing is essential in the absence of performance tests for respirator certification conducted in workplace or simulated-workplace settings.[97] (underlining added)

Yet the current DSR NPRM proposes continued use of the decades-old, invalid, and unreliable isoamyl acetate test for evaluating face-seal effectiveness of each "new" particulate respirator.[98] By what public health logic did DSR conclude that the testing requirements of Subpart R are now "nonessential" and can be dispensed with for another three years, which is five years after the NIOSH policy stated this testing was essential. The best DSR hopes to do is to propose a rule for a "simulated workplace protection factor test" for face-seal effectiveness testing in "early 1997."[99]

It is useful to examine the chronology of workplace protection factor (WPF) testing in DSR. DSR personnel initiated workplace testing of respirators in late 1981 at the General Battery Corporation in Reading, Pennsylvania. Workplace testing of respirators

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[96] The Wall Street Journal, (February 9, 1990), p. R5.

[97] Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992), page 392.

[98] 59 FR 26850 (May 24, 1994), page 26884, §§ 84.181 and .182.

[99] Ibid., page 26851.

by DSR personnel continued through the mid-1980s. In mid-1987 based on almost 6 years of DSR workplace-testing experience, the Director of DSR repeatedly promised the Director of NIOSH that DSR personnel could write a "workplace or simulated workplace testing" protocol. On that basis, NIOSH proposed a "workplace or simulated workplace testing" requirement in the first NPRM for 42 CFR Part 84 in August 1987.[100]

A month later, in September 1987, the regulated industry, represented by the Industrial Safety Equipment Association, Inc. (ISEA), immediately protested to NIOSH as follows:

> As set forth at 42 C.F.R. §84.31 through §84.34, the proposed rule requires workplace or simulated workplace testing prior to certification. The preamble to the proposed rule states that NIOSH will provide applicants detailed model protocols to perform these tests upon request. The preamble further states that NIOSH "has begun to develop model protocols for performing such tests in a proven and reliable manner." . . .
>
> The preamble states NIOSH's intention, however, to make the protocols available at the time of final rulemaking. NIOSH thereafter solicits comments on these unidentified model tests that will supposedly "assure reliability and reproducibility of mandatory workplace and simulated workplace test results."
>
> The foregoing proposal for workplace testing protocols is insufficient and should be recalled for further development. . . . Accordingly, the proposed rule denies the opportunity for informed comment and criticism and the notice is therefore defective.[101]

In January 1988, in reply to the ISEA protest that NIOSH had no workplace test protocol for it to comment on, the Director of DSR stated for NIOSH at a public hearing on the first NPRM:

> NIOSH is concerned that a NIOSH-specified protocol could limit flexibility and chill innovation in the development of improved products. Field testing of respirators is not a new, or untried idea. Over the past 15 or more years, substantial field testing of respirators has occurred in the respirator community both in the United States and internationally.[102]

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[100]52 FR 32402 (August 27, 1987), §§ 84.31 through 84.33, pp. 32408-32410.

[101]Koches, PA. Letter to Mr. John Moran, Director, Division of Safety Research, NIOSH, from Mr. Paul Koches of Wickens, Koches & Cale, Washington, DC (September 21, 1987), page 2.

[102]Moran, JM. *NIOSH Statement for the Record, Informal Hearings, Notice of Proposed Rulemaking, 42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices.* (January 20, 1988), page 7.

However, a month later in February 1988, a NIOSH committee consisting primarily of DSR staff, wrote the following:

> Although we believe in the philosophical importance of workplace or simulated workplace testing, the committee has serious concerns regarding the technical feasibility of respirator field testing as currently required in 42 CFR 84 and whether it is possible to require a pass/fail field testing without a validated methodology. Therefore, we suggest that a working group be established within NIOSH to consider all aspects of 42 CFR 84 dealing with field testing.[103]

Then, 9 years after DSR personnel started field testing and 3 years after professing "serious concerns" regarding "the technical feasibility of respirator field testing as currently required in 42 CFR 84," DSR personnel rushed forward with a 3-day technical conference in January 1991.[104] In part, the purpose of the conference was to:

> . . . solicit and present the available research and recommendations concerning the following questions: (1) The feasibility and practicality of developing a detailed protocol . . . for conducting workplace protection factor tests that would apply to all workplace settings, . . .[105]

Now, in 1994, over 3 1/2 years after DSR's technical conference, over 6 years after the "serious concerns" of DSR personnel, and over 12 years after the start of field testing by DSR personnel, DSR still does not have a validated protocol for simulated workplace testing of respirator so that American respirator users can be assured of their masks' face-seal effectiveness. But DSR personnel "anticipate" that such a protocol can be ready by early 1997, which is 3 years from now. DSR's early 1997 target date for **proposed** workplace-testing requirements is 5 years after DSR's technical conference, 9 years after DSR's "serious concerns" of early 1988, 16 years after the start of field testing by DSR personnel, and almost 25 years after the start of "substantial field testing" in the US and abroad.

Is this what DSR personnel consider "expeditious" protection of American respirator users? What are the problems at NIOSH's Division of Safety Research that are creating the inexcusable delays in protecting American respirator users? Is the problem lack of

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[103]Reed, LD. Letter to Dr. Murray Cohen, Acting Director, Division of Safety Research, NIOSH from Mr. Laurence D. Reed, Chairman, Respiratory Protection Committee (February 5, 1988), page 1.

[104]55 FR 42482 (October 19, 1990).

[105]Ibid., p. 42482.

scientists? Lack of resources? Lack of proper supervision and management? Perhaps part of the answer regarding the problems at NIOSH's DSR is indicated in replies given on survey forms submitted in response to a mid-1993 survey of NIOSH employees.[106] One DSR employee noted:

> DSR is in total chaos. Why don't you check the number of DSR employees who have sought counseling?[107]

NIOSH should immediately withdraw DSR's NPRM of May 1994 until the problems with its Division of Safety Research are rectified or regulatory reform is assigned to another part of NIOSH.

**DSR personnel have proposed that users of disposable masks receive significantly less assurance of face-seal effectiveness than provided to users of respirators with replaceable filters.**

During the face-seal tightness test, the NPRM proposes to use absolutely no "exercise" protocol for masks "with filters not intended to be replaced" (§ 84.181). In contrast to disposable masks, test subjects wearing those respirators "with replaceable filters" (§ 84.181) have to perform a 5-minute work schedule in the test chamber. This is absurd and irresponsible. Why should DSR personnel propose that users of the more common filtering-facepiece disposable masks (e.g., 3M 9970) and "maintenance-free" masks receive significantly less assurance of face-seal effectiveness than users of masks with replaceable filters?

NIOSH should immediately withdraw DSR's NPRM of May 1994 and correct glaring errors like this one.

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[106]Becks, et al. *Quality Philosophy Survey Report—Report of the Organizational Climate Survey Team.* Report submitted to the NIOSH Leadership Team (December 6, 1993).

[107]Ibid., p. 36.

**DSR personnel have failed to remedy a fundamental public health problem created by inadequate sample size.**

The issue of adequate sample sizes for testing face-seal effectiveness is thoughtlessly and carelessly omitted from the NPRM. NIOSH policy stated in 1992:

> All current certifications were originally issued on the basis of test results from a limited number of samples. For example, many laboratory tests are performed on only three samples. For this sample size, only when 63% or more of a particular model is ineffective will a sample of three have a substantial chance of rejecting the ineffective model. For the 7,000+ makes and models granted NIOSH certifications under Part 11, the certification means only that at least 37% of each make and model met the test requirements of Part 11 at the time of the original testing, if the tested samples were representative of each production make and model. This problem will be addressed by new statistical methodology and increased sample size given in § 84.229.

However, the assurance of respirator effectiveness that would have been provided by § 84.229 was deliberately omitted by DSR from the current NPRM. The 1992 NIOSH policy also stated with regard to sample size:

> The fundamental public health problem with current certification sampling plans is that they cannot assure that users will receive certified components or devices containing a low percentage of "failures." This problem has two basic causes. First, a binomial response variable (e.g., pass or fail) is used for the decision protocol even though the performance tests yield quantitative results. Second, by converting quantitative results to binomial data, a considerable amount of performance information is "thrown away" from the sample.[108]

This fundamental public health problem with current certifications has not been corrected in the DSR NPRM. DSR is proposing to perpetuate the problem into future NIOSH certifications, which is public health fraud committed on millions of American respirator users and purchasers. Neither § 84.181 nor § 84.182 state the number of test subjects required to be used by DSR personnel. Given the track record of DSR personnel over the last two decades, it would be foolhardy to leave this to the discretion of the DSR branch chief in charge of approval testing. NIOSH should immediately withdraw DSR's NPRM of May 1994 until glaring problems like this one are corrected so that American respirator users and purchasers are properly protected.

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[108]Leidel, NA: *Second Notice of Proposed Rulemaking—42 CFR Part 84, Revision of Tests and Requirements for Certification of Respiratory Protective Devices*. NIOSH, Atlanta, Georgia (August 1992), p. 385.

- **NIOSH should terminate all current Federal certifications for respirators and withdraw from its regulatory role as the "watchdog" agency for 7 to 10 million American respirator users, if it is not able or willing to drastically improve the program's management and regulatory reform activities.**

The Director of NIOSH has regulatory and watchdog responsibilities for industrial respirators that are a higher duty and hold more public trust than those held by the Commissioner of the Food and Drug Administration (FDA) for medical devices. About 7 to 10 million American workers use NIOSH-certified respirators at some time to protect their lives and health. Most American workers must wear their NIOSH-certified respirators as an involuntary condition of employment. They have no choice but to put their trust in NIOSH-certified respirators to protect themselves against toxic and lethal workplace conditions.

The purposes, uses, and protective functions of NIOSH-certified respirators equal and exceed those functions of medical devices regulated by the Food and Drug Administration (FDA) under the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938. As defined in current OSHA regulations, NIOSH-certified respirators are used:

> . . . in the control of those occupational diseases caused by breathing air contaminated with harmful dust, fogs, fumes, mists, gases, smokes, sprays, or vapors.[109]

Respirators certified by NIOSH meet several FDA regulatory criteria for Class II and Class III medical devices. These include criteria such as:

> . . . general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness . . . the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of health.[110]

For the past 16 years, the manufacturer of a FDA-regulated medical device has had to demonstrate both the safety and efficacy (i.e., adequate performance) of the device to receive the necessary government approval before marketing. Demonstrating efficacy means that appropriate testing indicates the device actually does what the manufacturer

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[109] 29 CFR 1910.134(a)(1).

[110] 21 CFR 860.3(c)(2) and (3).

says it will. The 1976 Medical Device Amendments, FDA regulations, and stringent FDA enforcement policies are intended to protect consumers because the complexity of the technology prohibits them from personally assessing the safety and efficacy of the medical devices used to prevent and treat their illnesses.

NIOSH's respirator certification responsibilities parallel FDA's approval responsibilities for medical devices. NIOSH-approved respirators are Federally certified for the prevention of sickness and death in the workplace. **The nature and technology of industrial respirators prevent users and purchasers from directly assessing the *safety and efficacy* of the NIOSH-approved respirators they wear and purchase. Thus American respirator users and purchasers must trust the scientific competence and integrity implicit in NIOSH certifications.**

Respirator users, health and safety professionals, and respirator purchasers place heavy reliance and trust on NIOSH's Federal certifications when they purchase respirators. For example, Howard J. Cohen, corporate manager of industrial hygiene services for Olin Corporation, made the following statement to an industry trade publication in 1989:

> Most users really can't distinguish between a good and a marginal device. They rely on NIOSH certification, which is like an Underwriters' Laboratories' approval.[111]

For many years, occupational safety and health texts have contained reassuring statements such as the following:

> Approved respirators provide adequate respiratory protection against the particular hazards for which they are designed, in accordance with the standards. The U.S. Department of Interior, Mining Enforcement Administration, and the U.S. Department of Health, Education, and Welfare, National Institute for Occupational Safety and Health, are recognized as authorities for approving respirators.[112]

Additionally, a major respirator manufacturer has for several years placed an advertisement in health and safety journals that states in large bold letters,

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[111]Minter, S. G.: Breathing New Life Into OSHA's Respirator Rule, Occupational Hazards **51**(5):89–93 (May 1989).

[112]Anton, T. J.: Occupational Safety and Health Management, McGraw-Hill Book Company, New York, New York (1979), p. 176.

**TO MEASURE SAFETY, COMPANIES COMPARE THEIR RESPIRATORS WITH THIS STANDARD**

followed by a picture of a NIOSH/MSHA certification label.[113]

If NIOSH is not ready, willing, or able to provide FDA-style testing and enforcement to protect American respirator users and purchasers, then it should terminate all current Federal certifications for respirators and withdraw from its regulatory role as a "watch-dog" agency. It appears that the FDA would do a far better job of protecting American respirator users and purchasers than has been done by NIOSH over the last 22 years.

[113]North Safety Equipment advertisement, Occupation Hazards **51**(3):4 (March 1989).

# APPENDIX A

## Invalid NIOSH Approval and Certification

## for the 3M 9970 HEPA Respirator

## Due to Two Major Procedural Errors

## During the 1987 NIOSH Certification Approval Testing

### Executive Summary

The fundamental purpose of NIOSH testing under 30 CFR Part 11 is to establish and assure respirator users and purchasers of the effectiveness and safety of any NIOSH-certified respirator. Based on the facts detailed in this appendix, any reasonable person would judge the improper certification of the 3M 9970 by NIOSH in 1987 as an irresponsible act that defrauded American respirator users and purchasers of the explicit regulatory protection embodied in any Federal certification issued by NIOSH to a respirator manufacturer. NIOSH personnel compromised and diminished user protection specified in NIOSH regulatory and science policy requirements. A reasonable person would conclude that NIOSH personnel and management were negligent in the invalid approval and certification of the 3M 9970 because there was a apparent failure to exercise due care and professional diligence appropriate for NIOSH's approval and certification of the 3M 9970. NIOSH should immediately annul and revoke Federal approval certifications TC-21C-437 and OUS TC-21C-438 for the 3M 9970 HEPA.

### Background

In early 1992, Dr. Leidel requested copies of the original NIOSH certification records (performance tests, quantitative results, and management decisions) for Federal approval certifications #TC-21C-437 and OUS [outside the United States] TC-21C-438 issued by NIOSH in 1987 for the 3M 9970 HEPA disposable mask. Nonconfidential NIOSH files

were provided to Dr. Leidel by the Certification and Quality Assurance Branch (CQAB), which is part of NIOSH's Division of Safety Research (DSR). The background section of the files reads in part:

> On July 16, 1987, 3M requested aproval (sic) of their 9970 disposable half mask respirator for dusts, fumes and mists having a time weighted average [exposure limit] 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).[1]

NIOSH personnel subsequently performed five series of approval tests on 3M 9970 samples:

1. DOP for single filters (§ 11.140-11) (3 masks tested at 32 L/min for 5 to 10 seconds each and 3 masks tested at 85 L/min for 5 to 10 seconds each)

2. Facepiece test (§ 11.162-3) (10 subjects tested)

3. Silica dust for replaceable filters (§ 11.140-4) (3 masks tested)

4. Exhalation valve leakage test (§ 11.140-10) (3 masks tested)

5. Corn oil fit test (unspecified in 30 CFR Part 11) (10 subjects tested)

Two of the five test series (#2 and #5) relate to the 3M 9970's face-seal protection effectiveness. That is, how much leakage can occur past a respirator's face seal (a.k.a. facepiece)? This type of leakage (as opposed to *filter leakage*) is known as an *inadequate respirator fit* or simply *inadequate fit*. For a negative-pressure, HEPA-filter mask such as the 3M 9970, effectively all mask leakage will occur past the mask's face seal, since HEPA filters are effectively 100% effective with essentially 0% filter leakage and exhalation-valve leakage. Therefore, test series #2 and #5 bear directly on the 9970's effectiveness and protection afforded 9970 users.

With regard to test series #2, the qualitative facepiece-leakage test (a.k.a. qualitative fit test or QLFT), NIOSH personnel committed a minor procedural discrepancy. The NIOSH records note the facepiece tightness test from 30 CFR 11.162-3 was performed on 10 subjects. However, the § 11.162-3 test is from Subpart L of NIOSH's regulation

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[1]Test files TN03846 and TN0347, NIOSH, DSR, COAB (September 4, 1987), page 1.

for chemical cartridge respirators and is not specified for particulate respirators such at the 9970. Subpart K of the Part 11 regulation requires the use of § 11.140-2 for dust, fume, and mist respirators like the 9970.

It appears that NIOSH's use of the unauthorized § 11.162-3 test might be marginally more protective for respirator users. It was later explained to Dr. Leidel that the § 11.162-3 test was run on the 3M 9970 based on administrative instructions from Ms. Nancy Bollinger (then Chief of NIOSH's certification branch) because it was a "longer test."[2] In fact, the test in § 11.162-3 is only marginally longer, since it requires that each test subject be exposed for 8 minutes to isoamyl acetate (a.k.a. banana oil) versus the 5-minute exposure required in § 11.140-2.

**Two Major Procedural Errors Invalidating the 3M 9970's NIOSH Certification**

More important however, are the two major procedural errors that invalidate the 1987 NIOSH approval and certification of the 3M 9970. These errors occurred during NIOSH's approval of the 3M 9970 test results from the #2 and #5 test series. The first major procedural error occurred during NIOSH's improper evaluation of the § 11.162-3 test results from the #2 test series. The 9970's certification records test state in part for the § 11.162-3 test criterion:

> One test subject will be allowed to detect the odor of isoamyl acetate as per policy memo, Nancy Bollinger, Assistant Chief, TCB.[3]

NIOSH's DSR was unable to find or provide a copy of this policy memorandum from the early 1980s.[4] Hence, any alleged justification for the one-subject waiver is unknown at this time. However, the regulatory test requirement for § 11.140-2 definitively states in part:

> . . . the odor of isoamyl-acetate <u>shall not be detectable by any wearer</u> during the test.[5] (underling added for emphasis)

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[2]Phone conversation on March 3, 1992 between Dr. Leidel, Mr. Richard Metzler (chief of the certification branch), and Mr. Chris Coffey).

[3]Test files TN03846 and TN0347, NIOSH, DSR, CQAB (September 4, 1987), page 1.

[4]Phone conversation on March 3, 1992 between Dr. Leidel, Mr. Richard Metzler (chief of the certification branch), and Mr. Chris Coffey.

[5]30 CFR 11.140-2(b)(3).

The regulatory test requirement for the § 11.162-3 test used by NIOSH definitively states in part:

> Each wearer shall not detect the odor of isoamyl-acetate vapor during the test.[6] (underlining added for emphasis)

It appears that the one-subject waiver from the §§ 11.162-3 and 11.140-2 regulatory requirements granted to the 3M Company by NIOSH was never submitted for regulatory amendment so that it could undergo public comment by all affected parties. It is unknown if the waiver was ever approved by DSR management or NIOSH management. It is unknown how broadly the waiver was applied to other manufacturer's respirators. The one-subject waiver appears to be an unauthorized, improper, and invalid reduction in respirator-user protection by NIOSH DSR personnel, since it directly contradicts, compromises, and diminishes an explicit certification-approval regulatory requirement in § 11.63, which states in part:

> Each respirator and respirator component shall when tested by the applicant and by the Bureau, meet the applicable requirements set forth in Subparts H through M of this part.

The invalidity of the one-subject regulatory waiver is directly relevant to the current invalidity of the 3M 9970's NIOSH approval and certification, since NIOSH test results for the 3M 9970 reveal that the eighth subject failed the § 11.162-3 face-seal leakage test. Therefore, under the 30 CFR Part 11 regulation, the 3M 9970 failed at least one of the four explicitly-required approval tests and should have never been granted a NIOSH certification in 1987.

The second of two major procedural errors that invalidate the NIOSH's 1987 approval of the 3M 9970 occurred during NIOSH's improper evaluation of test series #5, the "corn oil fit test," which is a quantitative face-seal fit-leakage test (a.k.a. QNFT). The corn oil QNFT is not described in 30 CFR Part 11. It was stated to Dr. Leidel that the corn oil test was conducted on 10 subjects wearing the 3M 9970 under the regulatory authority of 30 CFR 11.63, which states in part:

> In addition to the minimum requirements set forth in Subparts H through M of this part, the Bureau and the Institute reserve the right to require, as a further condition of approval,

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[6] 30 CFR 11.162-3(e)(3)

> any additional requirements deemed necessary to establish the quality, effectiveness, and safety of any respirator used as protection against hazardous atmospheres.

Initially it might appear that NIOSH's use of the corn oil QNFT during the 9970 testing process might provide extra protection and assurance to respirator users and purchasers with regard to the 3M 9970's face-seal effectiveness and protection. However, an invalid and improper test criterion was used by NIOSH personnel for the 1987 corn oil test. The 9970's certification records state the following approval criterion for the corn oil test:

> Maximum allowable leakage during a 5 minute test is 10 percent.[7]

It appears that the 10%-maximum leakage criterion was used because a mask such as the 3M 9970 has had a NIOSH-recommended *assigned protection factor* (APF) of 10 (i.e., maximum of 10% leakage during use) for almost the last 18 years.[8,9] However, the 10%-maximum leakage criterion used in 1987 by NIOSH personnel to evaluate the 9970's effectiveness was 10 times higher, hence 10 times less protective, than that required by NIOSH science policy at the time of the approval tests.

A 1%-maximum leakage criterion for both QLFT and QNFT results on negative-pressure halfmask respirators such as the 3M 9970 had been established by NIOSH over 5 years before the 1987 certification tests. The 1%-maximum leakage criterion had been recommended and utilized by both NIOSH and respirator manufacturers such as the 3M Company as early as 1981.[10] NIOSH stated to OSHA in 1981:

> QNFT provides equivalent protection for full-facepiece wearers and half-facepiece wearers, but the proposed QLFT protocols [e.g., 3M Company saccharin test] provide less protection for fullface mask wearers than for halfmask wearers. To attain the required protection factor of 10 for halfmask wearers, the proposed protocols are designed to pass only those

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[7]Test files TN03846 and TN0347, NIOSH, DSR, CQAB (September 4, 1987), page 2.

[8]Leidel, NA: *Respirator Decision Logic—Joint NIOSH/OSHA Standards Completion Program*. Appendix F in *A Guide to Industrial Respiratory Protection*, (August 1975) in NIOSH Technical Report #76-189 (June 1976), Appendix I, section A.

[9]Myers, WR, NJ Bollinger, TK Hodous, NA Leidel, SH Rabinovitz, and LD Reed: *NIOSH Respirator Decision Logic*, NIOSH publication #87-108, Cincinnati, Ohio (May 1987), Table 1, page 13.

[10]Leidel, NA: *Requirements for Respirator Fit Testing in the OSHA Lead Standard*. NIOSH Report to the Occupational Safety and Health Administration for Docket H-049A (October 1981).

> fits with protection factors of 100 [QNFT fit test results less than 1% leakage] (at the time of the one test under the limited range of determinant variables used in the QLFT protocols). Following this strategy of a 10-fold "safety factor," . . .[11] (underlining added for emphasis)

In 1982, 5 years before NIOSH's approval of the 9970 test results, NIOSH stated to OSHA and the respirator-user community:

> NIOSH chose to estimate the screening error rates of the QNFT and QLFT fit factor screening tests at screening levels of 1% leakage (fit factor of 100) for halfmasks and 0.2% leakage (fit factor of 500) for fullface respirators. These values were selected for several reasons . . . The fit factors determined by quantitative fit test methods reflect the optimal performance of only the tested respirator and cannot be considered equivalent to the TWA working protection factors that will likely be much lower.
>
> Second, the proponents of the 3M Company saccharin, the Du Pont isoamyl acetate, and the irritant smoke screening tests assert that their qualitative fit tests have been "validated" and have the ability to efficiently screen any fit factors less than 100 (those exceeding 1% leakage). Third, NIOSH believes that a "scale-down" factor must be applied to fit factors obtained during quantitative fit tests, when trying to achieve a high probability of attaining mandated TWA working protection factors in the work place. At present there are insufficient studies available to verify that a scale-down factor of 10, as reflected in the screening levels of 100 for halfmasks [1%-maximum leakage] and 500 for fullface respirators, is adequate for attaining the mandated TWA working protection factors. Fourth, NIOSH believes that screening levels of 10 [10%-maximum leakage] for halfmasks and 50 for fullface respirators can lead to substantially inadequate respiratory protection for workers. . . . It is insufficient health protection for workers to use screening levels of 10 for halfmasks . . . (underlining added for emphasis)
>
> Thus a screening level of 10 [10%-maximum leakage] is inappropriate for a fit testing program, when one is attempting to obtain a high probability that a TWA working protection factor of 10 is consistently achieved for each halfmask wearer in the workplace. A fit factor of 10 [10%-maximum leakage on a QNFT] for a halfmask wearer is unacceptable, since it does not indicate a high probability that a TWA working protection factor of 10 would be

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[11]Ibid., page 28.

consistently achieved for the halfmask wearer in the workplace.[12] (underlining added for emphasis)

It appears that the inadequate and insufficient 10%-maximum leakage criterion applied to the 9970's corn oil test results approved by NIOSH personnel was never submitted for regulatory amendment so that it could undergo public comment by all affected parties. It is unknown if this improper leakage criterion was ever approved by DSR management or NIOSH management. Use of the 10%-maximum leakage criterion appears to be an unauthorized, improper, and invalid reduction in respirator-user protection by NIOSH's DSR personnel, since it directly contradicts, compromises, and diminishes explicit NIOSH scientific policy in effect at the time of the 1987 approval testing.

The invalidity of the 10%-maximum leakage criterion used by NIOSH personnel in 1987 is directly relevant to the current invalidity of the 3M 9970's NIOSH approval and certification, since NIOSH test results for the 3M 9970 reveal that 3 of 10 subjects exceeded 1% leakage during the corn oil test—subjects #3, 4, and 8. Therefore, under the 30 CFR Part 11 regulation, the 3M 9970 failed a second approval test and should have never been issued a NIOSH certification in 1987.

One might argue, why all the concern about some wearers that cannot achieve an adequate fit with 3M's 9970 mask?[13] After all, isn't that why employers must fit test prospective users and why users must perform fit checks after every mask donning before use?[14] The fallacy in these arguments is that there are no foolproof fit tests nor any foolproof fit checks for identifying those 9970 users with inadequate fits. In fact, the best available evidence indicates that the 3M 9970 cannot be reliably qualitatively fit tested and it cannot be reliably fit checked. Warnings have been repeatedly issued to respirator purchasers and users regarding the many problems inherent in trying to assure a reliable and effective face seal with filtering-facepiece masks such as the 9970. With regard to

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[12]Leidel, NA: *Supplemental Report to OSHA for Docket H–049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users*. NIOSH Report to the Occupational Safety and Health Administration (October 1982), pp. 3-4.

[13]At the 95% confidence level, the NIOSH corn oil QNFT results indicate that between 9% and 62% of a 9970-user population represented by the 10 test subjects measured by NIOSH will not achieve less than 1% leakage. Hence between 9% and 62% of the population would have an inadequate fits with the 9970. Other user populations may achieve better or worse results with the 3M 9970.

[14]OSHA respiratory protection program regulatory requirements 29 CFR 1910.134(e)(5).

the saccharin qualitative fit test recommended by the 3M Company for use with its 9970 mask, NIOSH concluded in 1982:

> With the 3M saccharin protocol, there can be a substantial risk to wearers with fit factors less than 100 [exceeding 1% leakage], that they will be erroneously passed by this screening test.[15]

With regard to the fit check procedure recommended by the 3M Company for use with its 9970 mask, Appendix B of these comments demonstrates that there are no definitive data indicating that the 3M 9970 can be effectively fit checked. Appendix B also:

1. Corroborates OSHA's 1986 policy position that disposable respirators "can not be fit checked each time the same or new respirator is donned" and that "as a class, disposable respirators do not provide a reliable face fit after initial fit testing."[16]

2. Corroborates the warning given in the 1992 professional standard of care for respiratory protection programs that the positive-pressure fit check "may be difficult or impossible to carry out on valveless [filtering-facepiece] respirators."[17]

3. Indicates that the D. C. Circuit Court of Appeals was correct in 1987 in upholding OSHA's position that DM-filtering-facepiece respirators cannot be reliably checked for a proper fit.[18]

Therefore, test series #2 and #5, which evaluated the 3M 9970's face-seal effectiveness, are directly relevant to respiratory effectiveness and protection afforded 9970 users. Since the ability of fit tests and fit checks to reliably identify those users with inadequately fitting 9970s is highly questionable and unproven, it is critical that NIOSH approval

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[15]Leidel, NA: *Supplemental Report to OSHA for Docket H–049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users*. NIOSH Report to the Occupational Safety and Health Administration (October 1982), page 8.

[16]White, FA. Letter from the OSHA Deputy Assistant Secretary to P. G. Nash of Ogletree, Deakins, Nash, Smoak and Stewart. Washington, D.C., September 5, 1986, p. 8.

[17]ANSI Z88.2–1992—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § A.6.2, p. 24.

[18]National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987), p. 492.

testing assure that most 9970 users will be able to achieve a fit with less than 1% leakage.

The fundamental purpose of NIOSH testing under 30 CFR Part 11 is to establish and assure respirator users and purchasers of the effectiveness and safety of any NIOSH-certified respirator.[19] Based on the preceding facts detailed in this appendix, any reasonable person would judge the improper certification of the 3M 9970 by NIOSH in 1987 as an irresponsible act that effectively defrauded American respirator users and purchasers of the explicit regulatory protection that is supposed to inherent in a Federal certification issued by NIOSH. NIOSH personnel compromised and diminished user protection specified in NIOSH regulatory and science policy requirements.

A reasonable person would conclude that NIOSH personnel and management were negligent in the invalid approval and certification of the 3M 9970 because it appears that there was a failure to exercise due care and professional diligence appropriate for NIOSH's approval and certification of the 3M 9970. There is the appearance of a failure to exercise that degree of care rendered appropriate for the particular circumstances of NIOSH's approval process and public health responsibilities, and which a person of ordinary prudence in the same situation with equal experience and knowledge would not have omitted. There is also the appearance of an unreasonable lack of skill applied in professional duties related to the approval of the 3M 9970.

[19] 30 CFR 11.1 and 11.63(c).

**Specific Recommendations**

1. NIOSH should immediately annul and revoke Federal approval certifications TC-21C-437 and OUS TC-21C-438 for the 3M 9970 HEPA.

2. NIOSH should publish notification of this revocation in CDC's *MMWR—Morbidity and Mortality Weekly Report*.

3. NIOSH should send out a Respirator User Notice concerning this revocation to the respirator user and purchaser community.

4. NIOSH should require the 3M Company to send letters to all affected purchasers of its 9970 mask notifying them of the revocation of its NIOSH certification.

Nelson A. Leidel, Sc.D.
8-1-94

# APPENDIX B

## Beta-Error Analysis

## for 3M Company Fit-Check Methodologies Applied

## to Three 3M Company Filtering-Facepiece (Disposable) Respirators

### Executive Summary

There are no definitive data indicating that the 3M 9970 can be effectively fit checked with 3M's fit check. This $\beta$-error analysis corroborates OSHA's 1986 policy position that disposable respirators "can not be fit checked each time the same or new respirator is donned" and that "as a class, disposable respirators do not provide a reliable face fit after initial fit testing." Second, this $\beta$-error analysis corroborates the warning given in the 1992 professional standard of care for respiratory protection programs that the positive-pressure fit check "may be difficult or impossible to carry out on valveless [filtering-facepiece] respirators." Third, this analysis indicates that the D. C. Circuit Court of Appeals was correct in 1987 in upholding OSHA's position that DM-filtering-facepiece respirators cannot be reliably checked for a proper fit.

### Background

Fit-check efficacy data presented by 3M Company researchers in 1988[1] have been analyzed for fit check $\beta$-errors on three models of disposable respirators (3M 8710 DM-filter, 3M 9920 DFM-filter, and 3M 9970 HEPA-filter respirators). Developed by NIOSH in 1981 for comparing the efficacy of quantitative and qualitative fit tests, $\beta$ is an estimate of the probability of erroneously judging an unacceptable fit factor as acceptable, when the fit factor leakage at the time of testing actually exceeds the necessary

[1]Hendricks, L, et al. Effectiveness of fit check methods on half mask respirators. San Francisco: paper presented at the American Industrial Hygiene Conference, May 15-20, 1988.

screening level (e.g., >1% fit factor leakage, which is a fit factor less than 100).[2] That is, $\beta$-estimates characterize the error rate of fit tests or fit checks in relevant populations—those that have inadequate fits. Marsh at the Los Alamos National Laboratory has stated:[3]

> The most important statistic in evaluating the effectiveness of a qualitative fitting test from the standpoint of worker's health is the probability of a false negative among those workers with inadequate fits. This statistic is frequently called the beta error.

Any fit test or fit check must demonstrate a very low $\beta$ error because of health considerations. The estimated $\beta$ for a fit check indicates the proportion of wearers with inadequate fits that are incorrectly passed by the fit check (i.e., go undetected by the user performing the fit check).

The 3M Company has contended that both the 3M positive-pressure fit check and the 3M saccharin qualitative fit test (QLFT) are independently adequate to do the job.[4] 3M's claim is made in face of the warning given in the 1992 professional standard of care for respiratory protection programs, which states:

> A positive air-pressure fit check can be used on respirators equipped with tight-fitting respiratory-inlet coverings that contain both inhalation and exhalation valves. This test may be difficult or impossible to carry out on valveless [filtering-facepiece] respirators.[5]

Both fit tests and fit checks are used to test filtering-facepiece respirators for any inadequate face-seal fits. *Fit tests* and *fit checks* have the identical purpose—to detect inadequate fits (i.e., excessive leakage past a respirator's face seal). The reason that *fit tests* are not used exclusively by employers (i.e., respirator purchasers) and users (employees) has been summarized by the D. C. Circuit Court of Appeals as follows:[6]

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[2]Leidel, NA: *Requirements for Respirator Fit Testing in the OSHA Lead Standard*. NIOSH Report to the Occupational Safety and Health Administration for Docket H-049A (October 1981).

[3]March, JL. Evaluation of saccharin qualitative fitting test for respirators. Am Ind Hyg Assoc J. 1984; 45(6):371-376, p. 373.

[4]National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987), p. 492.

[5]ANSI Z88.2-1992—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § A.6.2, p. 24.

[6]National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987), p. 492.

> As 3M conceded at oral argument, the saccharin [fit] test is intended for use every three or six months; the test, administered at these intervals, checks for alteration in a wearer's facial contours that might affect the fit of the respirator. OSHA observed that 'it is not appropriate to require the employers to conduct the saccharin QLFT each time the respirator is worn since it is time consuming . . .' 50 Fed.Reg. 51154 (1985). Unsurprisingly, 3M does not press for such a requirement, one likely to increase the cost, and reduce the attractiveness, of its product to employers.

Therefore, since both fit tests and fit checks have the same function and purpose, they both should be evaluated against the same fit-factor screening criterion used to define an "adequate fit." For at least the last decade, respirator professionals have recommended that employers assure that each halfmask user achieve a fit factor of at least 100 (i.e., 1%-maximum leakage for QNFT results) in order to assure a working protection factor in the workplace of at least 10 (i.e., less than 10% total leakage into a user's mask).[7] That is, a "safety factor" of 10 must be used to convert a desired workplace protection to the appropriate fit-factor screening value used for fit tests. For example, a 1992 professional standard of care for respiratory protection programs states the following with respect to fit-factor acceptance criteria,

> If a quantitative fit test is used, a fit factor which is at least 10 times greater than the assigned protection factor (Table 1) of a negative pressure respirator shall be obtained before that respirator is assigned to an individual. If a qualitative test is used, only validated protocols are acceptable. The test shall be designed to assess fit factors 10 times greater than the assigned protection factor.[8]

Thus the $\beta$-errors for fit-check data reported by the 3M Company were estimated using a fit-factor screening criterion of 100 (i.e., inadequate fits defined as those with more than 1% QNFT leakage), which is what the saccharin fit test has been alleged to achieve.[9,10] In its 1988 report, the 3M Company incorrectly evaluated their

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[7]Leidel, NA: *Supplemental Report to OSHA for Docket H-049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users*. NIOSH Report to the Occupational Safety and Health Administration (October 1982), pp. 16-20.

[8]ANSI Z88.2-1992—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § 8.1.1.

[9]Leidel, NA: *Requirements for Respirator Fit Testing in the OSHA Lead Standard*. NIOSH Report to the Occupational Safety and Health Administration for Docket H-049A (October 1981).

recommended fit checks against a fit-factor criterion of only 10 (i.e., inadequate fits defined as those with more than 10% QNFT leakage), which failed to incorporate the "safety factor" of 10 used for fit testing.

Based on the available 3M data for the 3M 8710 DM-filtering-facepiece respirator, the best point estimate of $\beta$ for the positive-pressure fit check recommended by 3M is given by $9/12 = 0.75$.[11] That is, 75% of the 8710's inadequate fits would not be detected by 3M's recommended fit check. However, the margin of statistical sampling error this point estimate is quite wide due to the small sample size. The margin of sampling error is estimated with the 95% confidence interval estimate for the true $\beta$ error of 3M's fit check applied to the 3M 8710 mask, which is 0.45 to 0.93 in this case. That is, the best one can conclude from the 3M Company sample of 12 inadequate fits is that the best available data indicates that 3M's positive-pressure fit check, when conducted under optimal training and application conditions similar to those in the 3M study, would not detect between 45% to 93% of the inadequate fits of the 3M 8710 DM-filtering-facepiece respirator.

Based on the available 3M data for the 3M 9920 DFM-filtering-facepiece respirator, the best point estimate of $\beta$ for the positive-pressure fit check recommended by 3M is given by $4/11 = 0.36$.[12] That is, 36% of the 9920's inadequate fits would not be detected by 3M's recommended fit check. However, the 95% confidence interval estimate for the true $\beta$ error of 3M's fit check applied to the 3M 9920 mask is given by 0.14 to 0.67. That is, the best one can conclude from the 3M Company sample of 11 inadequate fits is that the best available data indicates that 3M's positive-pressure fit check, when conducted under optimal training and application conditions similar to those in the 3M study, would not detect between 14% to 67% of the inadequate fits of the 3M 9920 DFM-filtering-facepiece respirator.

Based on the available 3M data for the 3M 9970 HEPA-filtering-facepiece respirator, the best point estimate of $\beta$ for the positive-pressure fit check recommended by 3M is given

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[10](...continued)

[10]Leidel, NA: *Supplemental Report to OSHA for Docket H-049A: Evaluation of Quantitative and Proposed Qualitative Screening Tests for Inadequate Fit Factors of Respirator Users*. NIOSH Report to the Occupational Safety and Health Administration (October 1982).

[11]Hendricks, et al. Effectiveness of fit check methods on half mask respirators. San Francisco: paper presented at the American Industrial Hygiene Conference, May 15-20, 1988, Figure 1.

by 0/4 = 0.00.[13] That is, none of the 9970's inadequate fits would not be detected by 3M's recommended fit check. However, the 95% confidence interval estimate for the true $\beta$ error of 3M's fit check applied to the 3M 9970 mask is given by 0.00 to 0.53. That is, the best one can conclude from the minimal 3M Company sample of only 4 inadequate fits is that the best available data indicates that 3M's positive-pressure fit check, when conducted under optimal training and application conditions similar to those in the 3M study, would not detect between 0% to 53% of the inadequate fits of the 3M 9970 HEPA-filtering-facepiece respirator. Therefore, there are no definitive data indicating that the 3M 9970 can be effectively fit checked with 3M's fit check.

This $\beta$-error analysis corroborates OSHA's 1986 policy position that disposable respirators "can not be fit checked each time the same or new respirator is donned" and that "as a class, disposable respirators do not provide a reliable face fit after initial fit testing."[14] Second, this $\beta$-error analysis corroborates the warning given in the 1992 professional standard of care for respiratory protection programs that the positive-pressure fit check "may be difficult or impossible to carry out on valveless [filtering-facepiece] respirators."[15] Third, this analysis indicates that the D. C. Circuit Court of Appeals was correct in 1987 in upholding OSHA's position that DM-filtering-facepiece respirators cannot be reliably checked for a proper fit.[16]

Nelson A. Leidel, Sc.D.
8-1-94

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[13]Ibid., Figure 3.

[14]White, FA. Letter from the OSHA Deputy Assistant Secretary to P. G. Nash of Ogletree, Deakins, Nash, Smoak and Stewart. Washington, D.C., September 5, 1986, p. 8.

[15]ANSI Z88.2-1992—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § A.6.2, p. 24.

[16]National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration. 825 F.2d 482 (D.C. Cir. 1987), p. 492.

# APPENDIX C

## Problem with 20 Years of NIOSH Certifications

## Under 30 CFR Part 11 for Dust and Mist Filter Masks

### HISTORY

1. For over 20 years, respirator **fit checks** (a.k.a. pressure-tightness tests, respirator sealing tests) have been considered an essential part of any respiratory protection program, particularly for negative-pressure, air-purifying masks.[1] They are a fundamental part of any program "generally recognized as safe and effective."

   Fit checks are performed by a wearer each time he or she puts on their respirator. In almost all cases they involve sharp inhalation (the "negative pressure test") or exhalation (the "positive pressure test").

2. In 1987, the U. S. Court of Appeals for the District of Columbia Circuit ruled that OSHA had correctly assigned an APF of 5 (instead of the usual 10 given to halfmasks) to those "disposable respirators" that could not be fit checked by wearers for adequate inhalation protection against cotton dust.[2] That is, certain "maintenance-free" halfmasks with filtering facepieces for which it is "difficult, if not impossible, for the wearer to cover the entire [filtering] surface area, but not the seal between the respirator and the wearer's face"[3] during the user fit check recommended by the manufacturer. The Federal court stated that

   > OSHA recognized that, in the case of [certain filtering-facepiece] disposable respirators, the worker's hands cannot effectively block intended air intake, and that intake only, while leaving unobstructed air taken in because of the respirator's improper fit.[4]

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1. 1969 ANSI Z88.2, American National Standard Practices for Respiratory Protection.
2. National Cottonseed Products Association v. Brock and Minnesota Mining and Manufacturing v. Occupational Safety and Health Administration, 825 F.2d 482 (D.C. Cir. 1987)
3. Ibid., p. 489, footnote 6.
4. Ibid., p. 492.

The Federal court also noted that

> Absent assurance of a respirator's proper fit, the NIOSH and ANSI ratings can reliably indicate only the efficiency of the filter, not the effectiveness of the entire respirator as it is used on the job.[5]

3. Our scientific case against CDC's 1990 recommendation of "particulate respirators" (PRs) relies heavily on our position that most disposable PRs cannot be reliably fit checked by wearers. Hence, their protective ability is unreliable.

4. A provision in 30 CFR Part 11 (§ 11.140, Table 9) requires that a dust and mist (DM) filter mask pass a "pressure tightness test." This is one of the tests prescribed for "performance and protection." This test requirement is footnoted with the phrase, "Test is required only where applicable." However, unlike five other performance tests prescribed in Tables 9 and 10 of § 11.140, Part 11 is totally devoid of any description of how to perform the "pressure tightness test." No requirements are given for either the number of respirators or number of persons that the respirators shall be tested on.

5. Recently I received a copy of a letter from Chris Coffey (Chief, Air Purifying Respirator Section, CQAB) to Mr. Niemeyer of Filcon Corporation.[6] Based on statements in that letter, I made an inquiry to CQAB as to the history of this test and how it is performed by NIOSH.

   For as long as Chris has been at NIOSH (ca. mid-1970s), his section has "performed a pressure tightness test" using only three masks on one person (the test technician). Basically, NIOSH checks to see if it is **feasible** to follow a manufacturer's instructions for performing a fit check on one person—a NIOSH technician. Note that NIOSH **does not evaluate the efficacy of the fit check.** Then, if "NIOSH determines that it is feasible to conduct a pressure-tightness test on a respirator, the manufacturer is required to submit instructions on conducting this test."

   It is important to recognize that CQAB performs this test "only on respirators where it is possible." That is, in the past NIOSH has issued certifications to respirators on

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5. Ibid., p. 493.

6. Coffey to Niemeyer letter of July 15, 1992.

which a pressure tightness test cannot be performed. That is, NIOSH has knowingly certified masks that cannot be fit checked as required by OSHA regulations.[7] It is likely that we did not require any warning to a user that the mask could not meet Federal respirator-use requirements. The NIOSH rationale used for this "exemption" is the Table 9 footnote requiring the test only "when applicable." Also note that this test affects only what language must go in the user instructions for a respirator. In no way does the test determine whether or not a mask receives or is denied a NIOSH certification.

6. Because NIOSH has performed this test (on one person) and subsequently required a manufacturer to include instructions on the fit check with the mask, a manufacturer can make a strong case that NIOSH has approved the feasibility of their fit check and implicitly has approved the efficacy of that fit check. In effect, NIOSH is saying the 1987 Federal court ruling and OSHA were wrong.

7. Since the 1972 Part 11 has no instructions how to perform the pressure tightness test, I looked at the 1971 NPRM for our regulation. Nope, nothing there. However, the immediate regulatory predecessor to Part 11 for filter masks was the BuMines' 30 CFR Part 14. It was there that I found how the Bureau had performed the pressure tightness test. Apparently, when writing the 1971 NPRM to replace Part 14, someone had forgotten to include the following description of the test as previously detailed in 30 CFR 14.30(a) as follows (ca. late 1960s):

> *Pressure-tightness test (applicable to all respirators designed for respiratory protection against dust, fumes, and mists).* The complete respirator shall be fitted to the faces of 15 to 20 persons having a wide variety of facial shapes and sizes. To test the suitability of the fit of the respirator on these test subjects, the exhalation valve and the inhalation port(s) shall be held closed, and each subject shall exhale gently into the facepiece until a slight but definite positive pressure is built up in the facepiece. The absence of outward air leakage of air between the facepiece and the subject's face shall be evidence of acceptable fit of the facepiece.

However, the failure in 1971-72 to incorporate this language into NIOSH's 30 CFR 11.140 does not exonerate DSR personnel from adhering to the intent and specifics of the Bureau's § 14.30(a). When it assumed certification responsibilities in 1972, NIOSH hired several Bureau of Mines personnel in Pittsburgh who had been inti-

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7. 29 CFR 1910.134(e)(5)(i).

mately involved in certification testing under the 30 CFR Part 14 regulation. These personnel surely knew about the § 14.30(a) requirements from the 1960s.

**CONCLUSIONS**

A. NIOSH has been grossly incorrect in its performance of the § 11.140, Table 9 "pressure tightness test" for the last 22 years. First, the test has been performed only on one person—not the 15 to 20 persons used by BuMines before NIOSH. Second, NIOSH does not have a written protocol for this test. Third, in Coffey's letter to Niemeyer, no mention is made of a test subject noting any outward leakage during exhalation as required in the BuMines protocol. Fourth, NIOSH has not performed this test for the purpose stated by BuMines, to "test the suitability of the fit of the respirator" on the faces "of 15 to 20 persons having a wide variety of facial shapes and sizes" (i.e., a anthropometric fit test panel).

B. The 20-year-old requirement for a pressure tightness test is **unenforceably vague**, and has been since the day Part 11 was promulgated.

C. It is my professional opinion that the pressure tightness test as used by the BuMines was and is grossly invalid for the stated purposes of checking the fit on a wide variety of facial sizes.

D. I strongly recommend that NIOSH promptly issue both Manufacturers' and Users' Notices along the following lines:

• Effective immediately, NIOSH will no longer perform the pressure tightness test on any respirator submitted for certification since the requirement is **unenforceably vague.**

• Manufacturers, purchasers, and users must note that NIOSH's past performance of this test (and requirements that fit check instructions be included with each mask) are immediately voided. Manufacturers, purchasers, and users must recognize that a NIOSH approval number means that NIOSH has not evaluated nor approved any fit check test recommended by manufacturers. Manufacturers shall include a notice in all User Instructions that NIOSH has not evaluated nor approved any fit check test recommended in the instructions.

# APPENDIX D

## Draft Letter to Manufacturers of NIOSH/MSHA Certified Respirators and Draft Respirator Information Notice on Dust and Mist Respirators for Purchasers and Users of NIOSH-Certified Respirators

August 1992

**DRAFT LETTER TO ALL MANUFACTURERS OF NIOSH/MSHA CERTIFIED RESPIRATORS**

DSR's August 5, 1992
revised by Leidel as of August 16

The National Institute for Occupational Safety and Health (NIOSH) certifies respirators for protection against dusts and mists having a time-weighted average not less than 0.05 milligram per cubic meter or 2 million particles per cubic foot. In the past, as part of the certification process, NIOSH has conducted a pressure-tightness test as required in facepiece-test requirements of Table 9 of Title 30, Code of Federal Regulations, Part 11.140 (a.k.a. 30 CFR 11.140). For the last 20 years, this test has been performed only to assess the clarity of manufacturers' user instructions submitted under the requirements of § 11.33(a). However, with regard to any wearer-performed fit check test (a.k.a. face fit check, fit tests, face fit testing) recommended in an applicant's user instructions, NIOSH has never evaluated the efficacy, reliability, feasibility, and safety of such recommended fit check. NIOSH is concerned that the Institute's conduct of the pressure-tightness test and subsequent issuance of a NIOSH certification may mislead purchasers and users into believing that the Institute has evaluated and approved any fit check test or fit test stated in user fitting instructions.

More importantly, for the pressure-tightness test, 30 CFR 11.140 does not specify a test protocol, test parameters, pass/fail criteria, nor the number of test subjects that shall be used for this test. Unlike other facepiece-test requirements in Table 9 (i.e., isoamyl acetate test, §§ 11.140-1 and 11.140-2), the pressure-tightness test does not employ an anthropometric panel nor the use of a fit test agent to assess face-seal leakage. NIOSH's certification of a respirator's facepiece performance using the pressure tightness test does not indicate NIOSH's approval and acceptance of the respirator's facepiece performance.

Therefore, because 30 CFR 11.140 contains no regulatory specifications for performing the required pressure-tightness test,

NIOSH has concluded that this requirement is unenforceably vague. Effective immediately, the pressure-tightness test specified in 30 CFR 11.140, Table 9 will not be performed by NIOSH as part of the certification process. Passing this test will no longer be a certification test requirement. However, NIOSH will continue to examine clarity of the manufacturer's instructions for donning and fit checking. This certification policy does not modify nor diminish any other facefit test requirements specified in 30 CFR Part 11.

**Effective immediately, for all respirators currently certified under requirements in Table 9, 30 CFR 11.140, manufacturers shall include a written notice in all User Instructions that contains the following specific wording:**

> **''NOTICE—The National Institute for Occupational Safety and Health (NIOSH) has not evaluated nor approved the safety and efficacy of any methods recommended in these instructions for fitting this respirator to your face and checking your respirator's seal (fit) on your face. These methods may include any tests called 'fit checks,' 'face fit checks,' 'fit tests,' or 'face fit testing' or similar terms.**
>
> **It is your responsibility obtain an adequate fit (seal) of your respirator on your face every time you wear your mask for protection. If you cannot obtain an adequate fit (proper seal) with your mask, do not enter any contaminated or hazardous area''**

This user-instruction requirement is issued under the authority granted to the Institute in 30 CFR 11.33(c). This notification requirement is necessary so that (1) purchasers and users of NIOSH-certified respirators are clearly informed that the Institute has not evaluated and nor approved any fit check test or fit test stated in user instructions accompanying NIOSH-certified respirators, (2) users are clearly informed of their responsibilities so that they will use their mask in a safe and effective manner, and (3) users are clearly informed as to what actions they must take so that their respirator will be able to deliver the protection it is capable of providing.

Questions and comments should be directed to the Certification and Quality Assurance Branch, 944 Chestnut Ridge Road, Morgantown, WV 26505-2888, (304) 291-4334.

Sincerely yours,

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research

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DRAFT RESPIRATOR INFORMATION NOTICE
ON DUST AND MIST RESPIRATORS
for PURCHASERS AND USERS OF NIOSH-CERTIFIED RESPIRATORS

DSR's August 5, 1992
revised by Leidel as of August 16

The National Institute for Occupational Safety and Health (NIOSH) certifies respirators for protection against dusts and mists having a time-weighted average not less than 0.05 milligram per cubic meter or 2 million particles per cubic foot. In the past, as part of the certification process, NIOSH has conducted a pressure-tightness test as required in facepiece-test requirements of Table 9 of Title 30, Code of Federal Regulations, Part 11.140 (also known as 30 CFR 11.140). For the last 20 years, this test has been performed only to assess the clarity of manufacturers' user instructions submitted under the requirements of § 11.33(a). However, with regard to any wearer-performed fit check test (also

referred to by terms such as face fit check, fit tests, face fit testing) recommended in an applicant's user instructions, NIOSH has never evaluated the efficacy, reliability, feasibility, and safety of such recommended fit check. NIOSH is concerned that the Institute's conduct of the pressure-tightness test and subsequent issuance of a NIOSH certification may mislead purchasers and users into believing that the Institute has evaluated and approved any fit check test or fit test stated in user fitting instructions.

More importantly, for the pressure-tightness test, 30 CFR 11.140 does not specify a test protocol, test parameters, pass/fail criteria, nor the number of test subjects that shall be used for this test. Unlike other facepiece-test requirements in Table 9 (i.e., isoamyl acetate test, §§ 11.140-1 and 11.140-2), the pressure-tightness test does not employ an anthropometric panel nor the use of a fit test agent to assess face-seal leakage. NIOSH's certification of a respirator's facepiece performance using the pressure tightness test does not indicate NIOSH's approval and acceptance of the respirator's facepiece performance.

Therefore, because 30 CFR 11.140 contains no regulatory specifications for performing the required pressure-tightness test, NIOSH has concluded that this requirement is unenforceably vague. Effective immediately, the pressure-tightness test specified in 30 CFR 11.140, Table 9 will not be performed by NIOSH as part of the certification process. Passing this test will no longer be a certification test requirement. However, NIOSH will continue to examine clarity of the manufacturer's instructions for donning and fit checking. This certification policy does not modify nor diminish any other facefit test requirements specified in 30 CFR-Part 11.

Effective immediately, for all respirators currently certified under requirements in Table 9, 30 CFR 11.140, NIOSH is requiring manufacturers to include a written notice in all User Instructions that contains the following specific wording:

''NOTICE—The National Institute for Occupational Safety and Health (NIOSH) has not evaluated nor approved the safety and efficacy of any methods recommended in these instructions for fitting this respirator to your face and checking your respir-

ator's seal (fit) on your face. These methods may include any tests called 'fit checks,' 'face fit checks,' 'fit tests,' or 'face fit testing' or similar terms.

It is your responsibility obtain an adequate fit (seal) of your respirator on your face every time you wear your mask for protection. If you cannot obtain an adequate fit (proper seal) with your mask, do not enter any contaminated or hazardous area''

This user-instruction requirement is issued under the authority granted to the Institute in 30 CFR 11.33(c). This notification requirement is necessary so that (1) purchasers and users of NIOSH-certified respirators are clearly informed that the Institute has not evaluated and nor approved any fit check test or fit test stated in user instructions accompanying NIOSH-certified respirators, (2) users are clearly informed of their responsibilities so that they will use their mask in a safe and effective manner, and (3) users are clearly informed as to what actions they must take so that their respirator will be able to deliver the protection it is capable of providing.

Questions and comments should be directed to the Certification and Quality Assurance Branch, 944 Chestnut Ridge Road, Morgantown, WV 26505-2888, (304) 291-4334.

Sincerely yours,

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research

# APPENDIX E

## Transmittal Memorandum

## for Report Requested by Acting Director, NIOSH

## October 22, 1993

22 October 1993

From: Senior Science Advisor, OD, NIOSH

Subject: Final Analysis of Workplace Particle-Size Information Received in Reply to Ms. Porter's Email Request of June 16, 1993 to DPSE, DSHEFS, DRDS, and DSR

To:Dr. Richard Lemen
Acting Director, NIOSH

Back on June 21, 1993, you requested my analysis of the subject workplace particle-size information. On June 22, I sent you a preliminary memorandum on this issue (*1*). Attached to this memorandum is a 19-page report containing additional comments on the subject issue.

**Summary of analysis**

- In a wide range of workplaces and operations, workers are exposed to particle sizes under 3 $\mu$m AED (aerodynamic equivalent diameter) and particle mass distributions with <2-$\mu$m MMADs (mass median aerodynamic diameter (*2*)). Worker exposures to these "smaller particles" is not just a theoretical possibility.

- NIOSH does have ample data indicating that numerous workplaces contain aerosols with a substantial fraction of their total mass in the 0.2- to 3.0-$\mu$m AED size range. For a wide range of workplaces and operations, a mass leakage model I developed predicts substantial mass leakage through DM filters currently approved and marketed under the requirements of 30 CFR Part 11. For example, estimated filter leakage ranges from 3.5% to 26.1% mass leakage through the Gerson 1710 mask at 50 Lpm (refer to Figure 5 attached to the short report).

- The 1992 ANSI <2-$\mu$m-MMAD criterion for required use of HEPA-filters is inadequate and inappropriate for protection of workers wearing respirators. Thus the

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1. Leidel. Memorandum to R. Lemen: *Preliminary Comments on Particle-Size Information Received in Reply to Ms. Porter's Email Request of June 16, 1993 to DPSE, DSHEFS, DRDS, and DSR* (June 22, 1993).

2. For an aerosol with a mass median aerodynamic diameter of 2 $\mu$m, 50% of the total mass is contributed by particles with aerodynamic equivalent diameters less than 2 $\mu$m.

hazard of filter leakage cannot be dealt with by respirator purchasers by following the new ANSI recommendations. Therefore, NIOSH must continue to assume the responsibility for protecting respirator wearers from hazardous filter leakage via the implementation of lower APFs, tighter certification filter-test requirements, or some other reliable policy approach.

- Respirator manufacturers were incorrect when they stated at the June 15, 1993 meeting with NIOSH that adequate worker protection is created if employers use the ANSI criterion of <2 $\mu$m MMAD for requiring workplace use of HEPA filters. They stated that the total mass leakage through currently-certified DM filters is irrelevant for workplace with MMADs over 2 $\mu$m. These statements are contradicted by Figures 4 and 5 attached to my analysis.

- My analysis indicates that 0.2- to 3.0-$\mu$m-AED particles must be considered in any respirator-policy evaluation of workplace particle-size information.

- I do not have a definitive recommendation at this time for mass-distribution criteria to replace those of ANSI. However, two points should be made. First, my analysis indicates that ANSI's MMAD criterion for requiring use of HEPA filters should have been substantially above 2 $\mu$m, perhaps in the vicinity of 10 $\mu$m. Second, the ANSI-style criterion should have included a second criterion—the *geometric standard deviation* for the particle-mass distribution.

- NIOSH should not concede to respirator manufacturers that mass leakage through filters is relevant and count leakage per se is irrelevant for evaluating the toxicological hazard to wearers due to respirator-filter leakage. In fact, over a decade ago respirator experts warned NIOSH that submicron particles "are considered more hazardous per unit mass because their great numbers affect a greater area of the lung." Note that at the ANSI criterion of 2 $\mu$m MMAD, one can expect over 80% of all particles in a workplace aerosol to be less than 0.5 $\mu$m AED. These particles are the worst-leaking sizes through most DM and DFM filters (e.g., exceeding 75% count leakage). Essentially all of these particles are capable of reaching the deepest portions of a worker's lungs.

/s/ Nelson A. Leidel, Sc.D.

cc:

Ms. Porter
Dr. Bayse
Dr. Meinhardt
Dr. Stout
Dr. Doemeny
Dr. Fine
Dr. Meinhardt
Dr. Wagner
Ms. Bollinger
Dr. Amendola
Dr. Hodous
Mr. Metzler
Dr. Baron
Dr. Bartley
Dr. Kennedy
Dr. Haartz
Dr. Niemeier