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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

MAY 24 1993

FILE COPY

Patricia M. Rodenhausen
Regional Solicitor
U.S. Department of Labor
Office of the Solicitor
201 Varick Street
New York, New York 10014

Dear Ms. Rodenhausen:

This is in response to your letter dated March 16, concerning the distinctions between dust/mist (DM) respirators and dust/fume/mist (DFM) respirators. Because we are convinced that neither is adequate to fully protect, please understand that in developing our recommendations for health-care workers, we in the National Institute for Occupational Safety and Health (NIOSH) did not extensively analyze the difference between these two respirator types. Our full recommendations are contained in our document of September, 1992.[1]

The Institute's responses to your specific questions are contained in the enclosure to this letter. If I can be of any further assistance, please contact me.

Sincerely,

J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

DEPOSITION
EXHIBIT NO.
26
C.S.R., INC.

1. NIOSH. NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Atlanta, Georgia: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, September 14, 1992.

NIOSH RESPONSES TO QUESTIONS OF MARCH 16, 1993

FROM THE USDOL REGIONAL SOLICITOR, REGION II

It should be noted that your letter referred to "NIOSH-approved dust and mist (DM) and dust, mist, and fume (DMF) respirators." Strictly speaking, the terms DM and DMF[1] respirators are incomplete specifications for NIOSH-approved devices of the types we believe you are interested in. DM and DFM are two filter classes that are manufactured and NIOSH-certified in combination with two basic types of halfmask-facepiece types: (1) halfmask filtering facepieces[2] (with and without exhalation valves) and (2) filter-cartridge(s) mounted on elastomeric halfmask facepieces equipped with both inhalation and exhalation valves. In general, DM- and DFM-filtering-facepiece halfmasks are semi-rigid, cup-shaped devices. However, at least one NIOSH-approved, DM-filtering-facepiece halfmask is a pleated design that folds to a rectangular shape.

Filtering-facepiece respirators sometimes are generically described as "disposable," "maintenance-free," and "single-use" respirators. However, please realize that none of these three adjectives uniquely describe the types of masks you are interested in. The term "disposable" also encompasses some elastomeric halfmasks equipped with filter cartridges. The term "single-use dust respirators" should be reserved for only those

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1. A.k.a. DFM, which is the preferred acronym, since the phrase dust, fume, and mist is the regulatory phrase used throughout Subpart K of 30 CFR Part 11. DFM will be used in the remainder of this document.

2. For a *filtering-facepiece*, halfmask respirator, the mask's filter media forms an integral part of all or almost all of the facepiece. Frequently the facepiece construction features a nonwoven-fiber shell, conformable nose clip, and two latex head straps. All subsequent use in this document of the phrase *filtering-facepiece* will refer solely to halfmask respirators.

masks certified under the respirator class described in 30 CFR 11.130(h) and certified under the performance tests in 30 CFR 11.140-5. Because DM- and DFM-filtering-facepiece halfmasks are the least expensive and most common type of dust mask design, the following expert opinions in this letter regarding "DM" and "DFM" respirators will deal solely with filtering-facepiece halfmasks. NIOSH can provide expert opinions on elastomeric halfmask and fullface respirators equipped with DM- and DFM-cartridge filters, if this information is needed by the Solicitor.

It is also important to note the difference between "fit tests" and "fit checks." Fit tests are required by 29 CFR 1910.134(e)(5). Both qualitative fit tests (e.g., saccharin QLFT[3]) or quantitative fit tests (QNFT) must be performed by "competent persons" (i.e., qualified representatives of the employer) to (1) identify the "best-fitting" make, model, and size of respirator, (2) to "test its face-piece-to-face seal," and (3) to permit each wearer to "wear it in a test atmosphere." After the initial fit testing, a qualified employer (or qualified representative of the employer) should periodically fit test each respirator wearer (e.g., every six months, every twelve months[4,5,6]) to check for

3. 29 CFR 1910.1025, Appendix D.

4. ANSI. ANSI Z88.2-1980—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1980, § 7.2.3.2.

5. ANSI. ANSI Z88.2-1992—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § 8.1.4.

6. 29 CFR 1910.1025(f)(3)(ii).

alterations in a wearer's facial contours that might affect the fit of the respirator.[7] Refer to question #8 below for additional discussion of fit tests.

In contrast to infrequently-conducted fit tests, fit checks (e.g., positive-pressure fit check, PPFC) must be performed by respirator users each time they don their respirators as required by 29 CFR 1910.134(e)(5)(i). Because point-of-use factors can create a considerable risk of undetected hazardous leakage past a face seal, each wearer must have the capability of effectively and reliably checking his or her respirator for proper fit before every use.

The importance of fit checks for filtering-facepiece respirators is created in part by the inherent design and facepiece-adjustment procedures for these masks. For example, one DM-filtering-facepiece respirator, which is widely used in the United States, states in part the following "Fitting Instructions To Be Followed Each Time Respirator Is Worn":[8]

> "4. Place your fingertips from both hands at the top of the metal nosepiece. 5. Mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. Pinching the nosepiece using one hand may cause a bad fit and result in less effective respirator protection. Use two hands.

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7. 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).

8. 3M Company. Fitting instructions from carton side panels for the 3M 8710 respirator (NIOSH approval TC-21C-132, March 30, 1987). St. Paul, MN: 3M Occupational Health & Environmental Safety Division, 1993.

6. The seal of the respirator on the face should be fit-checked prior to each wearing. . . . If you CAN NOT achieve a proper fit DO NOT enter the contaminated area."

However, another manufacturer has stated:[9]

"Many people find metal strips uncomfortable, they need frequent fitting adjustments during the day, and can become misshaped if the worker doesn't adjust the strip or adjusts it incorrectly, or it has been deformed, the respirator will not seal properly."

Several popular models of DM- and DFM-filtering-facepiece respirators rely on a metal nosepiece to achieve a proper fit on each wearer.[10] Thus, there is a critical requirement for effective and reliable fit checking with these respirators. However, the fit-checking requirement cannot be met with these respirators. Refer to question #9 below for extensive discussion concerning why no DM- and DFM-filtering-facepiece respirator can be fit checked by their wearers.

One manufacturer (Uvex) has recently shown a device for covering the front of their filtering-facepiece respirators.[11] This 3-size device is intended to permit fit checking of

9. U.S. Safety Service Co. Product literature for the SoftSeal-D respirator (NIOSH approval TC-21C-291). Kansas City, MO: June 1985.

10. For example, but not limited to, 3M 8710, 8715, 9900, and 9920; Gerson 1710 and 1725.

11. American Industrial Hygiene Conference and Exhibition, New Orleans, LA, May 18-20, 1993.

their filtering-facepiece respirators. However, no data are available from the company to demonstrate the efficacy of their fit check procedures that are based on this new device.

In 1986, OSHA sent a response to a July 17, 1986 petition from the 3M Company, which had requested OSHA to reconsider and stay the respirator selection tables in OSHA's revised standards for asbestos (29 CFR 1910.1001).[12] The following statements from that response contain OSHA technical policy and positions on filtering-facepiece respirators (a.k.a. disposables) and HEPA filters that are pertinent to consideration for respiratory protection against TB contagion (i.e., transmission and infection by the airborne route).

> "The [asbestos] standards' respirator selection tables are intended to assure that workers exposed to a confirmed human carcinogen are provided with respirators that will provide optimal protection over the entire range of environmental conditions likely to be encountered. The OSH Act directs OSHA to 'set the standard which most adequately assures, [emphasis added] to the extent feasible, that no employee will suffer material impairment of health or functional capacity' and sets as a criterion for standards' attainment of the highest degree [emphasis added] of health and safety protection for the employee.' (Section 6(b)(5).)"[13]

12. 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.

13. Ibid., p. 2.

"Additionally, the [asbestos] standards prohibit the use of disposable respirators, with or without HEPA filters, because disposable respirators, in general, permit greater faceseal leakage under most conditions of use than half-mask respirators with elastomeric facepieces and replaceable filters, and thus they cannot be relied upon to provide optimal protection. 3M disputes both of these findings, but we believe there is substantial support in the record for both findings, including testimony from the National Institute for Occupational Safety and Health (NIOSH), respirator manufacturers, independent experts, industrial users of respirators, and labor unions, which represent the workers who must wear respirators. This evidence is buttressed by the Agency's collective experience promulgating and enforcing health standards."[14]

"In sum, the evidence in favor of HEPA filters over non-HEPA filters is substantial. Moreover, in the absence of conclusive evidence to the contrary, OSHA feels compelled to require the means which provide the greatest degree of protection, to the extent feasible, when dealing with a known human carcinogen like asbestos."[15]

". . . the evidence in the record strongly supports OSHA's finding that, when compared to elastomeric facepiece respirators, disposable respirators do not provide a reliable face fit during use. . . . the record clearly shows that, as a class, disposable

14. Ibid., p. 3.

15. Ibid., p. 7.

respirators do not provide a reliable face fit after initial fit testing. They cannot be adequately fit checked each time the same or new respirator is donned and they are more subject to abuse, misuse, and degradation of face fit during actual use than elastomeric facepiece respirators."[16]

"Workers unanimously opposed use of disposable respirators, contrary to 3M's assertion that workers find them more comfortable and are therefore more likely to use them. Workers stated that disposable respirators do not fit well (Tr. June 29, p.105). Dr. Mirer from the United Auto Workers stated that 'a field check . . . can't be performed on the paper dust mask' (Ex. 172A. p.13). See also Exs. 131, p.17; 134, p.2; 223, p.4; 277; 330; Tr. July 3, pp. 160-161, 193). . . . Dr. Morton Corn, a former OSHA Assistant Secretary and currently Professor of Environmental Health Engineering at the School of Hygiene and Public Health at Johns Hopkins University, said, 'We know that single-use [disposable] respirators, currently certified by NIOSH for asbestos, are associated with poor performance' (Tr. July 3, p.11) and '. . . of all the respirators I deal with, [disposables] seem to be the most improperly used in my experience' (Tr. July 3, p.45)."[17]

". . . a stay of the Agency's decision to require use of the most efficient filters would disserve the public interest by contravening Congress' mandate that OSHA 'assure so

16. Ibid., p. 8.

17. Ibid., pp. 9-10.

1. **What tests are entailed in the NIOSH certification of a respirator for DMF?**

DFM-filtering-facepiece respirators are certified in accordance with the requirements stated in Title 30, Code of Federal Regulations (30 CFR), Part 11 (copy enclosed). Included among the performance tests to certify DFM-filtering-facepiece respirators are the following requirements. The numbers in parenthesis are the appropriate regulatory sections.

- Silica dust [filter] test (§ 11.140-4)
- Lead fume [filter] test (§ 11.140-6)
- Silica mist [filter] test (§ 11.140-7)
- Exhalation valve leakage test (§ 11.140-10)
- Isoamyl acetate [face-seal]-tightness test (§ 11.140-1) (Refer to question #8 below for a discussion of the problems with evaluating results from this test.)
- Airflow resistance test (§ 11.140-9)

If the DFM-filtering-facepiece respirator does not have an exhalation valve, the following additional tests are conducted:

- Lead fume filter test for valveless respirators

  This is a special filter test conducted under the authority of § 11.63(c). It is identical to the lead fume filter test described in § 11.140-6 with the difference

being that a breathing machine as described in § 11.140-5 is used instead of a continuous flowrate of 32 Liters per minute (Lpm) to draw the lead fume through the respirator filtering facepiece.

- Silica dust [filter] test (§ 11.140-5)
- Silica mist [filter] test for valveless respirators

  This is another special filter test conducted under the authority of § 11.63(c). It is identical to the silica mist filter test described in § 11.140-7 with the only difference being that a breathing machine as described in § 11.140-5 is used instead of a continuous flowrate of 32 Lpm to draw the silica mist through the respirator's filtering facepiece.

However, please note that these filter and face-seal-tightness tests are invalid for judging respirator performance under most current use conditions in American workplaces, particularly those use conditions in hospitals using filtering-facepiece respirators. Also, there are substantial reliability and internal validity problems with the tests themselves. NIOSH researchers have published articles concluding that the current tests are "non-reproducible," are "insensitive" (i.e., cannot discriminate between poor and high efficiency filters) and "have gradually become irrelevant."[21,22] In particular, NIOSH scientists have noted that: ". . . the PbO

21. Moyer, ES. Respirator filtration efficiency testing. Fluid Filtration: Gas, Volume I, ASTM STP 975. Raber, RR, Editor. Philadelphia, PA: American Society for Testing Materials, 1986, pp. 167-180.

[lead] fume and SiO_2 [silica dust] aerosols [are] difficult to generate and maintain at a stable mass concentration and particle size for the length of the respective test runs (90 minutes for SiO_2 and 312 minutes for PbO)."[23] NIOSH has proposed changes to 30 CFR Part 11 to correct recognized problems in the certification test methodologies.

Most importantly, the silica-dust, silica-mist, and lead-fume filter tests are not representative of filter-use conditions that occur in hospitals. This is because filters used in hospital environments (e.g., in isolation rooms) will not achieve a condition known as "filter loading." *Filter loading* refers to a significant amount of airborne material being deposited on a filtering facepiece during use (e.g., the 150 to 200 mg of lead fume during the lead-fume certification test). Filter loading can have a marked effect on observed filtering-facepiece leakage values. In general, leakage decreases as filter loading increases. However, the opposite effect can occur for some special types of filters. Against respirable aerosols, clean filtering facepieces are generally the least protective, that is, as they originally come out of their protective plastic or box. This effect applies to widely-used, "mechanical" (non-electrostatic) filter media. Wilmes of the 3M Company stated in the early 1980s:

22(...continued)
22. Reed, LD, Smith, DL, and Moyer, ES. Comparison of respirator particulate filter test methods. J Intl Soc Resp Prot 1986; 4(3):43-60.

23. Ibid., p. 50.

"The current [30 CFR Part 11] certification tests only give an integrated value throughout the time period and provide little information on how much penetration occurs at any particular time. This element is important in that many of the filter media in existence today and in use in respirators have either good initial filter efficiency but the efficiency "degrades" when the filter begins to load with particulates due to the masking or loss of electrostatic charge or alternately other types have poor initial filter efficiency but the efficiency increases as filter becomes load (sic) or clogged."[24]

It must be recognized that essentially all filtering-facepiece respirators used in hospitals will achieve minimal filter loading during use. We can expect that most users of these devices will experience *higher filter leakages* than would be experienced in most conventional industrial environments, where some filter loading is expected and commonplace. Therefore, the filter-leakage results from any aerosol test that does not continuously monitor filter penetration from an "out-of-box" clean condition to a loaded condition should be considered suspect and generally invalid for accurately evaluating quantitative filter efficacy for filters to be used in hospital environments. In particular, this includes any results from NIOSH's silica-dust, silica-mist, and lead-fume filter tests. Only a special type of filter-leakage test, that (1) monitors instantaneous filter penetration throughout the test, (2) records the

24. Wilmes, DP. Recommendations to NIOSH for revision of 30 CFR Part 11, memorandum from chairman of the Ad Hoc Air-Purifying Committee of the ANSI Z88 Committee for Respiratory Protection, St. Paul, MN (undated, ca. early 1980s), p. 2.

maximum filter penetration achieved during such test, and (3) uses this maximum value as the performance result, should be used to evaluate filter efficacy for filters to be used in a hospital environment.

Note that the preceding discussion focused on filter leakage only. In order to accurately and validly evaluate the nature and extent of possible hazards to respirator wearers, it is essential to consider the total inward leakage, which is the sum of (1) filter leakage, (2) face-seal leakage, and (3) exhalation-valve leakage. For the remainder of these questions, NIOSH will assume that exhalation-valve leakage is negligible. However, this is not necessarily always the case in workplace usage of respirators.

The current NIOSH certification tests for any respirator do not quantitatively evaluate face-seal leakage. With regard to total respirator efficacy and reliability, NIOSH has stated the following with regard to the effects of face-seal leakage past surgical masks, DM-filtering facepieces, and DFM-filtering-facepiece respirators:

"Under optimal use conditions, up to 10% to 20% face-seal leakage is expected for any respirable aerosol (i.e., less than 10 micrometers aerodynamic diameter). Considerably more than 10% to 20% face-seal leakage is possible, since these masks cannot be properly fitted to each wearer's face with fit tests and fit checks. Face-seal efficacy with these masks is uncertain, since there are no proven fit tests for

them and they cannot be fit checked. Only one facepiece size is generally available that tends to produce higher leakages on small facial sizes (e.g., women, Hispanics, Asians)."[25]

At least one manufacturer (Uvex) does produce both their DM- and DFM-filtering-facepiece respirators in three sizes. However, essentially all other manufacturers of these devices produce each model in only one size.

Refer to the additional discussion below at question #9 for the rationale leading to the NIOSH and OSHA position that both DM- and DFM-filtering-facepiece respirators are incapable of being effectively fit checked with fit-check instructions currently provided by respirator manufacturers.

2. **What tests are entailed in the NIOSH certification of a respirator for DM?**

The following four performance tests are used to certify a DM-filtering-facepiece respirator, which are the same as those used in part to certify DFM-filtering-facepiece respirators:

25. NIOSH. NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Atlanta, Georgia: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, September 14, 1992, Table 2, p. 29.

- Silica dust [filter] test (§ 11.140-4)
- Silica mist [filter] test (§ 11.140-7)
- Exhalation valve leakage test (§ 11.140-10)
- Airflow resistance test (§ 11.140-9)

The isoamyl acetate tightness test and lead fume filter test are not used for DM-filtering facepiece respirators.

If the DM-filtering-facepiece respirator does not have an exhalation valve, the following additional two filter tests are conducted, which are the same as those used in part to certify DFM-filtering-facepiece respirators:

- Silica dust [filter] test (§ 11.140-5)
- Silica mist [filter] test for valveless respirators (This filter test is described under the DFM-filtering-facepiece respirator tests.)

Please note the discussion concerning the numerous problems with the silica-dust and silica-mist filter tests presented under question #1 above. Also note that the current NIOSH certification tests applicable to DM-filtering-facepiece respirators do not quantitatively evaluate face-seal leakage that must be considered in addition to filter leakage when total leakage into a respirator is being evaluated.

3a. **What does the lead fume test for DMF certification establish?**

The lead fume filter test for DFM-filtering-facepiece respirator certification establishes the fact that the filtering facepieces of three test respirators remove lead fume generated in the manner described in requirements of 30 CFR 11.140-6. This filter-only test is performed with each respirator face seal glued to the test apparatus and does not measure face-seal leakage. Refer to the response after question #1 for a discussion of why it is essential to also consider face-seal leakage when evaluating the total protection afforded by a filtering-facepiece respirator.

Over the 312-minute period of the lead-fume test, about 10 cubic meters of air containing 15 to 20 milligrams (mg) per cubic meter of lead oxide fume is passed through the filtering facepieces of three respirators. Thus each of the three filtering facepieces must filter out a mass of about 150 to 200 milligrams of airborne lead oxide fume. The certification performance criterion is that no more than a total of 1.5 mg mass of fume (from the total mass exposure of 150 to 200 mg to each respirator) can penetrate any of the three filtering facepieces during the entire duration of the test (i.e., less than 0.75 to 1.0% total mass leakage).

There are a number of ways of characterizing (1) the size of individual airborne particles and (2) polydisperse aerosols.[26] For individual particles, the preferred parameter for reporting size is *aerodynamic diameter* (a.k.a., aerodynamic equivalent diameter or AED). This is the term used almost universally in airborne particle research. When only diameter is reported for particle research results, it can be assumed it is the aerodynamic diameter because of the following reasons given by Hinds:[27]

"Aerodynamic diameter standardizes not only for shape but also for density. . . . If a particle has an aerodynamic diameter of 1 μm it behaves in an aerodynamic sense like a 1-μm water droplet regardless of its shape, density, or physical size. Furthermore, it is aerodynamically indistinguishable from other particles of different size, shape, and density having a aerodynamic diameter of 1 μm. . . . Aerodynamic diameter is the key particle property for characterizing filtration, respiratory deposition, and the performance of many types of air cleaners. In many situations, it is not necessary to know the true size, shape factor, and density of a particle if its aerodynamic diameter is known."

26. *Polydisperse aerosols* are collections of multiple-size solid or liquid particles suspended in a gas.

27. Hinds, WC. Aerosol technology—properties, behavior, and measurement of airborne particles. New York: John Wiley & Sons, 1982, pp. 49-50.

In contrast to individual particle sizes, *polydisperse aerosols* contain a range of particle sizes, often a very wide range, and statistical parameters must be used to characterize their size. These aerosol size parameters include *count median diameter* (CMD, a.k.a. count median aerodynamic diameter, CMAD) and *mass median diameter* (MMD, a.k.a. mass median aerodynamic diameter, MMAD).[28] For lognormally-distributed polydisperse aerosols, which is the general case, the MMD is always larger than the CMD, typically by a factor of about 3 to 5 or more depending on the variability of the size distribution (e.g., geometric standard deviation, GSD).

The lead fume used in this filter-only certification test has an count median diameter (CMD) of about 0.23 micrometer (μm).[29] That is, 50% of the lead fume polydisperse aerosol consists of particles with aerodynamic diameters greater than 0.23 μm. The other 50% of the lead fume aerosol consists of particles having aerodynamic diameters less 0.23 μm.

Note that the lead fume certification test measures only time-averaged mass leakage through a DFM filter under the specific conditions of the test. This test does not measure the numerical (count) leakage of individual particles (i.e., percentage of fume particles that penetrate through each tested DFM-filtering facepiece). These

28. Ibid., pp. 81-100.

29. Reed, LD, Smith, DL, and Moyer, ES. Comparison of respirator particulate filter test methods. J Intl Soc Resp Prot 1986; 4(3):43-60, p. 47.

latter parameters are the relevant indicators of filter performance for pathogenic biological aerosols such as droplet nuclei under 5 μm aerodynamic diameter.[30,31,32]

3b. **Does DMF certification using the lead fume test mean that 100% of particles with diameters in the 1-2 micron range will be captured by the respirator filter?**

For the reasons discussed under question #1 above, essentially nothing can be inferred from lead-fume test results with regard to either the DFM-filter efficiency or face-seal efficacy of DFM-filtering-facepiece respirators used in hospital environments against particles in the size range 1 to 2 μm aerodynamic diameter.

The lower limit to the particle size range of interest in question #3b was given as 1 to 2 μm. This infers that both OSHA and the DOL Solicitor assume that there are no droplet nuclei below 1 μm aerodynamic diameter that contain one or more viable tubercle bacilli. Thus there would be no hazard from particles less than 1 μm aerodynamic diameter. However, this may not necessarily be the case. The

30. The term "droplet nuclei" is aerobiology jargon describing aerosols (particles) containing one or more viable microbes such as tubercle bacilli.

31. Wells WF. Airborne contagion and air hygiene. Cambridge: Harvard University Press, 1955, p. 110.

32. Dimmick, RL. Stirred-settling aerosols and stirred-settling aerosol chambers. Chapter 7 in Dimmick, RL, Akers, AB. An introduction to experimental aerobiology. New York: John Wiley & Sons, 1969, p. 138.

aerodynamic diameter for infectious droplet nuclei may extend well below 1 μm aerodynamic diameter.

Only recently has the "particle size" for droplet nuclei containing tubercle bacilli been definitively given as 1 to 5 μm.[33] The citation for this size range was given as "Wells WF. Aerodynamics of droplet nuclei. In: Airborne contagion and air hygiene. Cambridge: Harvard University Press, 1955:13-9." However, Wells did not specify a lower size limit in his text. He did state that "Nuclei, settling less than 0.1 of a foot per minute in still air, penetrated to the lungs and were planted quantitatively upon the alveolar surfaces."[34] There is no evidence that consideration of filter leakage should be limited to only those particles with aerodynamic diameters of 1.0 μm or larger.

With regard to the filter-leakage component of total respirator leakage, only one research team has evaluated filter-only leakage in the unloaded condition for DFM-filtering-facepiece masks against particles in the respirable size range over 1 μm count median diameter (CMD).[35,36,37] Only two models of DFM-filtering-

33. 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), p. 3.

34. Ibid., p. 122.

35. Chen, CC, Willeke, K. Aerosol penetration through surgical masks. Am J Infec Control 1992; 20:177-84.

36. Chen, CC, Lehtimäki, M, and Willeke, K. Aerosol penetration through filtering facepieces and respirator cartridges. Am Ind Hyg Assoc J 1992; 53(9):566-74.

facepiece respirators were evaluated in the reported research: the 3M 9920 and Moldex 3400.

The oil aerosols used in the DFM-filter testing included 10 different count diameters in the range of 1 to 2 μm. For the Moldex 3400 DFM model tested at 30 liters per minute, the highest observed leakage in this size range was 4.4% for a 1.03 μm count median diameter (CMD) aerosol and the lowest observed leakage was 0.5% for a 1.98 μm CMD aerosol. For the 3M 9920 DFM model tested at 30 liters per minute, the highest observed leakage over the 1 to 2 μm CMD range was 0.1% for a 1.03 μm CMD aerosol and the lowest observed leakage was 0.004% for a 1.98 μm CMD aerosol. At 60 liters per minute for this 3M model, the reported leakage was 0.4% for a 1.03 μm CMD aerosol. These limited data from one research team indicate that the DFM-filter-only leakage for one or more DFM-filtering-facepiece respirators exceeds 0%. These data indicate that the DFM filters of one or more DFM-filtering-facepiece respirators are not 100% efficient against aerosols in the 1 to 2 μm size range.

With regard to the face-seal-leakage component of total respirator leakage, one must recognize there is leakage of up to 10% to 20% past the face seal in addition to the DFM-filter-only leakage discussed above. Refer to the discussion on this issue under

37(...continued)
37. Willeke, K and Chen, CC. Letters to N. A. Leidel and J. D. Millar of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01301, Cincinnati, OH, June 27, 1991, July 15, 1991, and October 12, 1992.

question #1. Therefore, to estimate the total inward leakage for DFM-filtering-facepiece respirators, one must add 10% to 20% to the DFM-filter-only leakages discussed above.

It should be noted that some questions have been raised as to whether filter and face-seal efficiencies against nonbiological aerosols (e.g., oil) substantially differs from those against viable biological particles of the same aerodynamic diameter (e.g., respirable droplet nuclei in the 1 to 5 μm size range that contain viable tubercle bacilli). Hatch and Wolochow have stated:[38]

"Microbial aerosols differ from other aerosols only in that some of the airborne particles contain living microorganisms; the presence of these life forms in no way invalidates the laws governing aerosol behavior discussed in previous chapters."

There are no data to support a contention of respirator-protection differences between inert nonviable aerosols and viable bioaerosols (a.k.a. biological aerosols) of the same aerodynamic diameter under the same use conditions. NIOSH recently queried the Commander of the U.S. Army Chemical Research Development and

38. Hatch, MT and Wolochow, H. Bacterial survival: consequences of the airborne state. In: Dimmick, RL and Akers, AB. An introduction to experimental aerobiology. New York: John Wiley & Sons, Inc., 1969:267-295, p. 267.

Engineering Center on this question and other issues. The following statements were made to NIOSH by the Army.[39]

"To assess mask filter performance against the chemical threat an aerosol penetrometer test apparatus is used. The challenge consists of an 0.3 micron monodispersed oil aerosol (e.g., Dioctyl Phthalate - DOP). A special test apparatus is also used to determine the biological agent aerosol protection capability of the filter. As with the bio-test for mask fit, Bg spores ranging from 1 to 5 microns in size are used."

"All the tests described above share a common characteristic, they utilize particulate aerosols as the challenge simulant. The fundamental physical laws and properties associated with both face seal and filter penetration of particulate aerosols should hold true regardless of whether the challenge is of non-biological or biological origin. With all other factors being equal, the efficacy of a particular respirator design should be comparable for any given non-reactive particulate challenge having a similar size and/or aerodynamic properties."

"The results of the analysis show similar protection factor performance between the Bg and corn-oil fit test methods; thus, lending support to the basic premise that

39. Sarponaro, AJ. Letter to S. Deitchman of NIOSH transmitting information on military respirator fit and filter efficiency testing for protection against chemical and biological agents, U.S. Army Edgewood Research, Development and Engineering Center, Aberdeen Proving Ground, MD, December 18, 1992.

aerosolized microorganisms, in a given size range, behave comparable to inert particulate challenges with regard to respirator fit."

3c. **If less than 100%, how much less?**

This is answered in the response to the preceding question #3b.

3d. **Does the percentage of particles captured decrease as the size approaches 1 micron?**

A. Yes for filter-only leakage through DFM-filtering facepieces. This filter leakage continuously increases in magnitude as the particle size decreases in magnitude until the most-penetrating particle size (about 0.2 to 0.4 μm aerodynamic diameter) is reached.

B. With regard to face-seal leaks, the percentage of particles that will enter a respirator through these leaks increases as the particle size decreases. The effect of particle size on percent penetration through seal leaks has been estimated by Hinds and Bellin,[40] who stated:

40. Hinds, WC and Bellin, P. Performance of dust respirators with facial seal leaks: II. Predictive model. Am Ind Hyg Assoc J 1987; 48(10):842-47.

"In the absence of any information about leak size or respirator pressure drop, the best single equation for predicting penetration is LPen = 97 - 7.4(d_a) for 0.1 ≤ d_a ≤ 12 μm where Lpen is penetration in percent and d_a is particle aerodynamic diameter in μm."

Their equation predicts an *average* of 60% penetration for 5 μm particles, 75% penetration for 3 μm particles, and 90% penetration for 1 μm particles. These values are only a rough estimate for any particular face-seal situation. A similar effect of particle size on face-seal-leak penetration was found by Holton and Willeke.[41] As with filter leakage, both studies indicate that the percentage of particles "captured" by face-seal leakage pathways decreases as the particle size decreases from 5 μm toward 1 μm aerodynamic diameter. That is, the percentage of particles passing through face-seal leakage pathways increases as the particle size decreases from 5 μm to 1 μm aerodynamic diameter.

Earlier studies by Schwabe and the 3M Company are consistent with the 1987 estimates from Hinds and Bellin.[42,43] Marsh has concluded that:

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41. Holton, P, Willeke, K. The effect of aerosol size distribution and measurement method on respirator fit. Am Ind Hyg Assoc J. 1987; 48(10):855-860.

42. Schwabe, PH. The measurement of face-seal leakage of respirators by gases and aerosols. Paper presented at the International Symposium on air pollution abatement by filtration and respiratory protection, Copenhagen, November 1980.

43. 3M Company. Post hearing data submission on qualitative fit testing protocols under the lead standard. St. Paul, MN, Minnesota Mining and Manufacturing Company, October 1981.

"These [Schwabe and 3M Company] studies show that facepiece leaks sufficient to produce a fit factor less than 100 [over 1% leakage] are large and non-filtering. Schwabe found that 10 holes 300 μm in diameter were required to produce a penetration of 2.5% (a fit factor of 40). A 3 μm MMAD aerosol will be able to penetrate facepiece leaks of this size without excessive loss due to interception, inertial impaction or sedimentation."[44]

3e. **If so, what is the percentage?**

Refer to the discussion under the preceding question #3d.

3f. **Is the answer based on experimental measurements or estimates?**

Experimental measurements reported in the cited studies.

3g. **If estimates, what is methodology used?**

The methodologies used are reported in the cited studies.

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

4a. **Although a DM certified respirator is not tested against lead fume, does it have the capability of capturing some particles in the 1-2 micron range?**

In general, all DM-filtering-facepiece respirators have the capability of capturing some particles in the range of 1 to 2 μm aerodynamic diameter.

4b. **If so, what is the percentage?**

With regard to the DM-filter-leakage component of total respirator leakage, researchers at two laboratories have evaluated DM-filter-only leakage in the unloaded condition for DM-filtering-facepiece masks against aerosols in the respirable size range over 1 μm. These are the Hinds laboratory at UCLA and the Willeke laboratory at the University of Cincinnati.[45,46,47,48,49,50] Hinds and Kraske (HK) used two sizes of oleic acid aerosol between 1 and 2 μm

45. Hinds, WC and Kraske, G. Performance of dust respirators with facial seal leaks: I. Experimental. Am Ind Hyg Assoc J 1987; 48(10):836-41, Figures 5 and 6.

46. Hinds, WC. Letters to L. W. Sparks and J. D. Millar of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01595, Los Angeles, CA, June 19, 1991 and October 25, 1992.

47. Ruuskanen, J, et al. Aerosol penetration characteristics for disposable respirator facepieces. J Aerosol Sci 1988; 19(7):1445-1448.

48. Chen, CC, Willeke, K. Aerosol penetration through surgical masks. Am J Infec Control 1992; 20:177-84.

49. Chen, CC, Lehtimäki, M, and Willeke, K. Aerosol penetration through filtering facepieces and respirator cartridges. Am Ind Hyg Assoc J 1992; 53(9):566-74.

50. Willeke, K and Chen, CC. Letters to N. A. Leidel and J. D. Millar of NIOSH transmitting filter-leakage data obtained during research activities supported in part by NIOSH Grant R01 OH01301, Cincinnati, OH, June 27, 1991, July 15, 1991, and October 12, 1992.

aerodynamic diameter to estimate DM-filter-only leakage: 1.042 and 1.675 μm. Ruuskanen et al. (R) used 1 and 2 μm corn oil aerosol to evaluate DM-filter-only leakage. Chen and Willeke (CW) used 10 sizes of corn oil aerosol between 1 and 2 μm to evaluate DM-filter-only leakage. Five models of DM-filtering-facepiece respirators were evaluated in the reports from the two laboratories: AO R1070, Gerson 1710, Moldex 2200, 3M 8710, and 3M 8715. The primary results for these respirators are summarized in the next table.

Make and Model of DM-Filtering Facepiece	Research Group	Particle Aerodynamic Diameter μm	Flowrate, liters per minute	Filter-Only Leakage
3M 8710	CW	1.03	10	0.52%
			30	2.1
			60	4.6
		1.48	10	0.10%
			30	0.56
			60	1.25
		1.98	10	0.04%
			30	0.25
			60	0.46
	HK	1.042	10	0.15%
			20	0.32
			50	1.8
		1.675	10	0.04%
			20	0.08
			50	0.59

Make and Model of DM-Filtering Facepiece	Research Group	Particle Aerodynamic Diameter μm	Flowrate, liters per minute	Filter-Only Leakage
3M 8715	CW	1.03	10	0.91%
			30	3.2
			60	6.1
		1.48	10	0.27%
			30	0.79
			60	1.4
		1.98	10	0.16%
			30	0.38
			60	0.50
	R	1.0	10	3.5%
			30	5.2
			50	8.5
		2.0	10	0.7%
			30	0.9
			50	1.5
AO R1070	HK	1 042	10	7.2%
			20	15
			50	14
		1.675	10	1.8%
			20	4.6
			50	3.3

Make and Model of DM-Filtering Facepiece	Research Group	Particle Aerodynamic Diameter μm	Flowrate, liters per minute	Filter-Only Leakage
Gerson 1710	CW	1.03	10	21%
			30	31
			60	35
		1.48	10	10%
			30	16
			60	15
		1.98	10	5.1%
			30	7.3
			60	5.6
	HK	1.042	10	12.7%
			20	18
			50	26
		1.675	10	5.4%
			20	7.3
			50	11
Moldex 2200	CW	1 03	10	7.3%
			30	13
			60	20
		1.48	10	5.0%
			30	6.8
			60	8.9
		1.98	10	4.1%
			30	4.4
			60	4.4

These numerous DM-filter-only data from two research teams indicate that the DM-filter-only leakage for several DM-filtering-facepiece respirators substantially exceeds 5% for three of the five models tested in the size range of 1 to 2 μm aerodynamic diameter. These DM-filter-only leakage values are substantially greater than the DFM-filter-only leakages discussed above under question #3b. These data indicate that the DM-filters of at least three of five tested DM-filtering-facepiece respirators are substantially less than 100% efficient against aerosols in the 1 to 2 μm size range (i.e., AO R1050, Gerson 1710, and the Moldex 2200).

With regard to the face-seal-leakage component of total respirator leakage, one must recognize there is leakage of up to 10% to 20% past the face seal in addition to the DM-filter-only leakage reported in the preceding table. Refer to the discussion on this issue under question #1. Therefore, to estimate the total inward leakage for DFM-filtering-facepiece respirators, one must add 10% to 20% to the DFM-filter-only leakages discussed above.

4c. **Does the percentage of particles captured decrease as the size approaches 1 micron?**

A. Yes for filter-only leakage through DM-filtering facepieces. As with DFM-filter, DM-filter leakage continuously increases in magnitude as the particle size decreases in magnitude until the "most-penetrating" particle size (about 0.2 to 0.4 μm CMD) is reached.

B. With regard to face-seal leaks, the percentage of particles that will enter a respirator through these leaks increases as the particle size decreases. Refer to the response after question #3d for a discussion of the effect of particle size on percent penetration through seal leaks.

4d. If so, what is the percentage?

Refer to the responses under the preceding parts of question #4.

4e. **Is the answer based on experimental measurements or estimates?**

Experimental measurements reported in the cited studies.

4f. **If estimates, what is methodology used?**

The methodologies used are reported in the cited studies.

5. **Respond to the Greater New York Hospital Association (GNYHA) statements that the silica dust has a particle size averaging 0.5 microns and in which 98% of the particles are less than 2 microns. GNYHA thus alleges that both DM and DFM would be expected to be highly effective against droplet nuclei.**

The Greater New York Hospital Association (GNYHA) was in error when it concluded:[51]

"Thus both types of respirators [DM and DFM] would be expected to be highly effective against droplet nuclei." . . . "If existing [NIOSH] tests are to be used as the standard for certifying respirators for protection against tuberculosis, then DM devices would seem to be equivalent to the DMF device."

NIOSH has found at least four serious technical errors in GNYHA's analysis. First, and most important, they failed to consider the debilitating reduction in protection caused by face-seal leakage around filtering-facepiece respirators. NIOSH certification tests for both the DM- and DFM-filtering-facepiece respirators do not include effective and reliable tests for face-seal efficacy on a representative range of facial sizes and shapes. Refer to material under question #8 for a discussion on this issue. This same testing deficiency applies to existing performance tests for surgical masks, which have addressed neither face-seal leakage nor the effects that prolonged use might have on this leakage.[52]

51. GNYHA. GNYHA position paper on OSHA's new DMF respirator requirements for the routine care of TB patients. New York, undated (ca. mid-1992), p. 2.

52. Davis, WT. Filtration efficiency of surgical masks; the need for more meaningful standards. Am J Infec Control 1991; 19:16-18.

Second, GNYHA failed to recognize that filtering-facepiece respirators cannot be fit checked, as required by OSHA's 29 CFR 1910.134(e)(5)(i).

Third, GNYHA failed to consider the reduction in protection that occurs with both DM- and DFM-filtering-facepiece respirators when they do not attain the unrealistic filter loading that occurs in during NIOSH's silica-dust testing.

Fourth, GNYHA mistakenly interpreted the mass efficiency measured by the NIOSH silica-dust test as a relevant indicator of DM- and DFM-filter efficiency, which it is not. Count efficiency is the relevant indicator for droplet nuclei. Count efficiency is not measured by the NIOSH silica-dust test. Note that *count efficiency* for a given filter is generally less than observed *mass efficiency* for the same filter at any given aerodynamic diameter. That is, the *count leakage* is generally greater than the observed *mass leakage*. This is because the larger particles in a polydisperse aerosol constitute substantially more of the total mass and are filtered out more efficiently.

NIOSH concludes that neither DM- nor DFM-filtering-facepiece respirators will provide highly effective protection against droplet nuclei. For DM-filtering-facepieces, there is substantial leakage both through the DM filters and past the face seals. For DFM-filtering facepieces, there is smaller, but significant, leakage through DFM filters in addition to substantial leakage past the face seals.

6. **GNYHA alleges that the lead fume test is characterized by a larger average particle than the silica dust test. Therefore, GNYHA alleges that DM devices would seem to be equivalent to DMF devices for protection against tuberculosis.**

GNYHA stated:[53]

"Indeed, a consult from a respirator manufacturer indicates that the lead fume test, used to distinguish DMF from DM respirators, is characterized by far more condensation of particles and therefore a larger average particle size than the silica dust test."

As previously stated for question #3a, NIOSH has reported that the lead fume used in the filter-only certification test has a count median diameter (CMD) of about 0.23 μm.[54] For the NIOSH silica dust, the size has been reported as 0.36 μm CMD.[55] Refer to material presented under the preceding question #5 for a rebuttal of the erroneous conclusion that DM-filtering-facepiece respirators would be equivalent to DFM-filtering-facepiece respirators for protection against airborne TB contagion.

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53. GNYHA. GNYHA position paper on OSHA's new DMF respirator requirements for the routine care of TB patients. New York, undated (ca. mid-1992), p. 2.

54. Reed, LD, Smith, DL, and Moyer, ES. Comparison of respirator particulate filter test methods. J Intl Soc Resp Prot 1986; 4(3):43-60, p. 47.

55. Ibid., p. 47.

7. **Please respond to the litany of reasons regarding the inappropriateness of the testing process given in the GNYHA letter.**

GNYHA Reason 1. Factual incorrectness of the enforcement guidelines and inappropriate recommendation of DFM respirators as the standard for worker protection.

Respirators with negative pressure inside the mask, including the DM-filtering-facepiece "particulate respirators" (PRs) recommended in the 1990 Centers for Disease Control (CDC) guidelines, will not assure a sufficient level of protection because of inward leakage of potentially contaminated air. Even under conditions of optimal use, particulate respirators may allow up to 20% leakage past the face seal.[56] Further, no filtering-facepiece respirator can be reliably fit-checked by wearers before each use. Thus, the actual protection provided by such devices for any individual is unreliable and unpredictable. Therefore, they are not recommended by NIOSH for protection against TB transmission. Only powered air-purifying half-mask respirators or positive-pressure air-line half-mask respirators are recommended by NIOSH to achieve effective and reliable protection against TB due to face-seal leakage considerations.

56. NIOSH. NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Atlanta, Georgia: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, September 14, 1992.

In addition, the data from the studies cited in the answer to questions #3 and #4 indicates that both DM- and DFM-filtering-facepiece respirators can exhibit significant leakage of particles in the submicron to 2 μm aerodynamic diameter size range. In general, DFM-filtering-facepiece respirators have less filter leakage than DM-filtering-facepiece respirators under the same conditions for particles in that size range.

GNYHA Reason 2. Inappropriateness of the testing process used to certify particulate respirators.

The Institute agrees that the testing process used to certify DM- and DFM-filtering-facepiece respirators is inappropriate for accurately predicting quantitative respirator performance against respirable droplet nuclei. This is one reason for NIOSH recommending only HEPA filters for filtering contagious air containing droplet nuclei. Additionally, there are no existing analytical methods for real-time monitoring of respirable droplet nuclei containing one or more viable tubercle bacilli so that filter leakage and respirator leakage studies could be conducted.

GNYHA Reason 3. Enforcement of specific practices that go beyond currently recommended infection control guidelines and the New York State Department of Health memorandum.

This is an enforcement policy issue.

GNYHA Reason 4. Overemphasis on the use of respiratory protective devices.

The Institute agrees that respirators should not solely be replied upon to prevent health-care-worker exposure to TB.[57] Respirators are the least desirable method for controlling exposure. In any place where workers are potentially exposed to droplet nuclei from a TB transmitter, the first and highest priority is to reduce the probability of exposure through the use of administrative controls and engineering controls. These include, but are not limited to, rapid identification, early treatment, isolation procedures, and negative-pressure ventilation for acid-fast bacilli isolation rooms, booths, hoods, tents, or other devices for containing droplet nuclei at the infectious patient.

However, it is unlikely that the exposure of workers to droplet nuclei can be completely controlled and adequately monitored for effectiveness at the infectious source even when these techniques are conscientiously implemented.

57. Ibid., Section III.B, pp. 10-15.

GNYHA Reason 5. Operational problems that hinder patient care and worker protection.

The Institute recognizes that there are certain application issues associated with the use of respirators in a health-care setting. The practical disadvantages of powered, air-purifying respirators were extensively discussed by NIOSH in section IV.F. of its September 14, 1992 report.[58] As the Institute noted at that time, "any disadvantages of the respirators recommended in these guidelines should be evaluated in the context of the aggregate of other isolation precautions already accepted and in use for potential tuberculosis transmitters."[59]

8. **Render an expert opinion on the fit testing characteristics of the DMF respirator compared to the DM respirator.**

NIOSH is unsure exactly what is meant by the phrase "fit testing characteristics." NIOSH interprets the question to inquire if there are fundamental differences in construction or design between DM- and DFM-filtering-facepiece respirators (other than the efficiency of their filter media) that somehow affects their ability to undergo or respond to a fit test or fit check. If this is the question, the answer is no. Neither NIOSH's certification tests nor any research articles published in the professional

58. Ibid., pp. 25-27.

59. Ibid., p. 26.

literature provide any data to show that DFM-filtering-facepiece respirators have different fit-testing or different fit-checking characteristics as compared to DM-filtering-facepiece respirators.

The fundamental and critical problem affecting fit testing of both DM- and DFM-filtering facepieces is screening-performance problems with the fit tests methodologies. That is, the ability of the tests to reliably and accurately detect inadequate fits. None of the three major fit tests currently accepted by OSHA[60] can assure that respirator wearers with *inadequate fit factors* (i.e., defined by OSHA as those fit factors less than 100 obtained with halfmasks) will be reliably and efficiently rejected by any of the three fit tests, which is what is claimed by the proponents of these fit tests. This has been NIOSH's conclusion since 1982.[61] However, note that even those wearers demonstrating a fit factor of 100 or more with their halfmasks must still be considered as have up to 10% respirator leakage during their workplace usages. Refer to material presented under the following question #9 for additional discussion of this issue and the issue of fit-checking.

60. Du Pont isoamyl acetate, 3M saccharin, and stringent irritant smoke.

61. NIOSH. Supplemental report to OSHA for docket H-049A: evaluation of quantitative and proposed screening tests for inadequate fit factors of respirator users, October 1982, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, p. 8.

In contrast to DM-filtering-facepiece masks, upon which no facepiece-tightness tests are performed, a qualitative iso-amyl acetate tightness test is conducted on modified DFM-filtering-facepiece respirators as part of the certification process.[62] The test is conducted on a panel of 10 subjects with varying facial sizes. The DFM respirators are specially modified so that all of the air that would normally be inhaled is drawn through an efficient canister or cartridge(s). There cannot be any interference with the face-contacting portion of the facepiece.

With regard to this tightness test, it should be noted that NIOSH uses an undocumented approval criteria that requires that no more than one subject fails the tightness test from out of the ten panel members tested. The statistical reliability of permitting one failure in ten subjects is very poor from a public-health standpoint. Only when a particular respirator is so bad that it will provide an ineffective fit to at least 39% or more of users, will the "9 passing out of 10" rule have a statistically significant chance of rejecting the respirator during the certification tightness-test. This means that the best NIOSH can say, based on available data from ten subjects for a certified mask, is that 61% or more of wearers of a certified respirator would pass the certification tightness-test at the time of testing. And this applies only if the face-seal fit characteristics of the specially-modified respirators were representative of those masks actually sold to purchasers.

62. 30 CFR 11.140-1.

Additionally, it is doubtful if the tightness test used by NIOSH during certification testing is capable of effectively detecting inadequate fits or face seals. A NIOSH analysis of the Du Pont isoamyl acetate test, which has a more stringent test protocol than the regulatory isoamyl acetate test used by NIOSH, concluded in 1982: "The Du Pont isoamyl acetate, 3M saccharin, and stringent irritant smoke protocols cannot assure that respirator wearers with fit factors less than 100 will be efficiently rejected by any of the three screening tests."[63]

9. **Render an opinion as to the ease with a DMF respirator as compared to a DM respirator can be checked for fit by user.**

Your cover letter states that ". . . it is OSHA's understanding that, due to their design, DMF respirators are easily tested by the wearer for fit." This is a misunderstanding on the part of OSHA. No DM- nor DFM-filtering-facepiece halfmask can be reliably fit checked by their wearers as required by 29 CFR 1910.134(e)5)(i) and recommended for almost a quarter of a century in respiratory protection programs professionally recognized as safe and effective.[64,65,66]

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63. NIOSH. Supplemental report to OSHA for docket H-049A: evaluation of quantitative and proposed screening tests for inadequate fit factors of respirator users, October 1982, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, p. 8.

64. ANSI. ANSI Z88.2-1969—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1969, § 7.5.

65. ANSI. ANSI Z88.2-1980—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1980, § 7.4 and Appendix A7.

One major type of fit check is the positive-pressure fit check (PPFC). The PPFC is generally recognized as effective for elastomeric facepieces equipped with both inhalation valves and exhalation valves. However, in both 1980 and 1992 it was stated in a national consensus voluntary standard that:

"This [PPFC] may be difficult or impossible to carry out on valveless respirators." . . . "Care must be taken in carrying out negative or positive/pressure fit checks. Thorough training in carrying out these tests should be given to respirator wearers."[67,68]

The problems associated with conducting a PPFC on a filtering-facepiece respirator arise from the design of these devices, whether or not they incorporate exhalation valves. With non-filtering-facepiece elastomeric respirators, which are generally equipped with both inhalation and exhalation valves, all air flow is supposed to pass through these one-way valves. However, with filtering-facepiece masks, the entire surface of the facepiece is intended to permit air intake and air out flow upon exhalation. For over 5 years, OSHA has recognized that, for the PPFC used with filtering-facepiece respirators as recommended in most manufacturer's instructions,

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66(...continued)

66. ANSI. ANSI Z88.2—Proposed American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § 7.3(7).

67. ANSI. ANSI Z88.2-1980—American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1980, § A7.3.

68. ANSI. ANSI Z88.2—Proposed American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, §§ A6.3 and A6.5.

"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."[69] Hence, in 1987 the Federal Appeals Court for the D.C. Circuit ruled that "We think it evident that OSHA did not rule without reason when it adhered to the view that no test appropriate for daily use adequately assured the proper fit for disposable [filtering-facepiece] respirators."[70]

Additionally, NIOSH has analyzed fit-check efficacy data reported by 3M Company researchers in 1988.[71] NIOSH estimated the β-error for two data sets reported by 3M. Developed by NIOSH in 1981 for comparing the efficacy of quantitative and qualitative fit tests, β 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 screening level. For halfmasks, this would be a fit factor leakage result exceeding 1%, which is a fit factor less than 100).[72] That is, β estimates the error rate of fit tests or fit checks in relevant populations--those

69. 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.

70. Ibid., p. 493.

71. 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.

72. NIOSH. Comments to OSHA for docket H-049A: Requirements for respirator fit testing in the OSHA lead standard, October 1981, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

that have inadequate fits. Marsh at the Los Alamos National Laboratory has stated:[73]

"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 β because of health considerations. The estimated β 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).

Both fit tests and fit checks are used to test filtering-facepiece respirators for adequate face fit. The 3M Company has contended that both the positive pressure fit check (PPFC) and the saccharin qualitative fit test are independently adequate to do the job.[74] As discussed in the introductory material preceding question #1, fit tests and fit checks have the identical purpose--to detect inadequate fits. The

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

74. 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.

rationale for companies and users not using only fit tests before every respirator use has been summarized in the D. C. Circuit Court opinion as follows:[75]

"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 in order to assure a working protection factor in the workplace of at least 10.[76] 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.

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75. Ibid., p. 492.

76. NIOSH. Supplemental report to OSHA for docket H-049A: evaluation of quantitative and proposed screening tests for inadequate fit factors of respirator users, October 1982, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, pp. 16-20.

For example, a 1992 proposal for a national consensus voluntary standard 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."[77]

Thus NIOSH evaluated the β-errors for fit-check data reported by the 3M Company against a fit-factor screening criterion of 100, which is what the saccharin fit test has been alleged to achieve.[78,79] In their 1988 report, the 3M Company incorrectly evaluated their recommended fit checks against a fit-factor criterion of only 10, which failed to incorporate the "safety factor" of 10 used for fit tests.

77. ANSI. ANSI Z88.2—Proposed American national standard practices for respiratory protection. New York, NY: American National Standards Institute, 1992, § 8.1.1.

78. NIOSH. Comments to OSHA for docket H-049A: Requirements for respirator fit testing in the OSHA lead standard, October 1981, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

79. NIOSH. Supplemental report to OSHA for docket H-049A: evaluation of quantitative and proposed screening tests for inadequate fit factors of respirator users, October 1982, OSHA Docket No. H-049A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

Based on the available 3M data for the 3M 8710 DM-filtering-facepiece respirator, the best point estimate of β for the PPFC recommended by 3M is given by 9/12 = 0.75. However, the margin of statistical sampling error around this point estimate is quite wide due to the small sample size of 12 inadequate fits. The margin of sampling error is estimated with the 95% confidence interval estimate for the true β, which is 0.45 to 0.93 in this case. That is, the best one can conclude from the limited sample of 12 inadequate fits is that the actual β-error rate for the PPFC conducted under conditions similar to those in the 3M study indicates that 45% to 93% of the inadequate fits would not detected by users performing the fit check on one model of a DM-filtering-facepiece respirator.

Based on the available 3M data for the 3M 9920 DFM-filtering-facepiece respirator, the best point estimate of β for the PPFC recommended by 3M is given by 4/11 = 0.36. The 95% confidence interval estimate for the true β is given by 0.14 to 0.67. That is, the best one can conclude from the limited sample of 11 inadequate fits is that the actual β-error rate for the PPFC conducted under conditions similar to those in the 3M study indicates that 14% to 67% of the inadequate fits would not be detected by users of the fit check on one model of a DFM-filtering-facepiece respirator

The preceding analysis demonstrates 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. Therefore, the face-seal efficacy with DM- and DFM-filtering-facepiece respirators is uncertain and problematic.

10. **Render an expert opinion as to the suitability or not of surgical masks (e.g., the Tecnolcone Classic and the Tecnol Fluid Shield Cone Classic II) for interdiction of particles in the 1-5 micron range.**

All filtering-facepiece surgical masks are totally unsuitable for protecting wearers against TB contagion. NIOSH's rationale for this conclusion has been summarized in the first column of Table 2 in the Institute's September 14, 1992 report.[80] Most statements from Table 2 for surgical masks are given in the quotation appearing near the end of the response to question #1. Most importantly, it must be recognized that filtering-facepiece surgical masks have the same fundamental flaw that afflicts DM- and DFM-filtering facepiece respirators— they are incapable of being reliably fit checked to detect inadequate fits. Thus these surgical masks cannot meet the requirements of OSHA's 29 CFR 1910.134(e)(5(i).

Additionally, the filter media of many surgical masks are not considered by NIOSH to be effective for removing particles in the 1 to 5 μm size range.

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80. NIOSH. NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Atlanta, Georgia: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, September 14, 1992, pp. 29-30.

A study by Tuomi[81] showed that a 3M Asptex and Johnson and Johnson surgical masks had efficiencies of about 10% (90% leakage) and 50 to 60% (50 to 40% leakage) respectively. These efficiencies were determined with corn oil aerosols in the 1 to 2 μm size range. In the submicron range the efficiencies decreased further.

Chen and Willeke[82] measured the penetration of a flat surgical mask and a molded-cone surgical mask as well as the DM- and DFM-filtering-facepiece respirators mentioned previously. At a flowrate of 10 Lpm against a 1 μm aerodynamic diameter particle, the flat surgical mask had a leakage of 80%. The leakage dropped to 60% against a 2-μm particle and against a 4-μm particle it was approximately 30%. The molded-cone surgical mask had a 30% leakage against a 1-μm particle. This decreased to approximately 10 to 15% leakage against a 2-μm particle and to almost 0% leakage against a 5-μm particle.

The Life Sciences Division of the Dugway Proving Ground gave a presentation to CDC on February 26, 1992, entitled "Biosafety in Biomedical Laboratories." In this presentation data was presented on challenging filtering-facepiece surgical masks with *Bacillus subtilis* var. *niger* (*B. globigii*), which has a size in the range of interest (size ranging from 1 to 5 μm aerodynamic diameter, with an average size of 1 to

81. Tuomi T. Face seal leakage of half masks and surgical masks. Am Ind Hyg Assoc J 1985; 46:308-312.

82. Chen, CC, Willeke, K. Aerosol penetration through surgical masks. Am J Infec Control 1992; 20:177-84.

2 μm[83]). This data indicated the surgical masks gave only 67% protection.

83. Sarponaro, AJ. Letter to S. Deitchman of NIOSH transmitting information on military respirator fit and filter efficiency testing for protection against chemical and biological agents, U.S. Army Edgewood Research, Development and Engineering Center, Aberdeen Proving Ground, MD, December 18, 1992, Enclosure #3, p. 1.