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Diane D. Porter
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Dear Ms. Porter:

Enclosed you will find my review of the NIOSH working draft document "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists." The issues discussed in the Working Draft encompass a broad variety of topics concerning aerosols and their measurement, health effects, behavior, etc. as well as respiratory protection and the methods used to evaluate their effectiveness in the field. I found that it was not possible to discuss each point raised in the document. Rather, I chose to focus my attention on several of the more important issues.

I would like to indicate that review of this document took a considerable amount of time, as I was required to read a number of studies on respirator filter and facepiece behavior. While I recognize that NIOSH relies on outside input from a variety of sources when developing new policies or determining how best to allocate its resources, I would suggest that some form of compensation should be considered when requesting a review of a document of this nature. I estimate that I must have spent at least 20-30 hr (at least 2-3 hr per day for 10 days) of my time in my review of this document. This is a considerable amount of time and is probably equivalent to the time spent by someone participating as a study section member when reviewing grant applications.

I was glad to provide this service to NIOSH and I hope my review will be of some use as you determine the application of this document in future policy-making efforts.

Sincerely,

Lisa M. Brosseau, Sc.D., CIH
Assistant Professor

January 15, 1993

Review of "A Performance Evaluation of DM and DFM Filter Respirators Certified for Protection Against Toxic Dusts, Fumes, and Mists." Working Draft, September 15, 1992. National Institute for Occupational Safety and Health.

Background

I have been requested to review this National Institute for Occupational Safety and Health (NIOSH) document by Diane D. Porter, Assistant Director for Legislation and Policy Coordination at NIOSH. Specifically, I was asked to consider the various assumptions supporting the evaluation, the independent research studies on filter leakage and the criteria by which the data from these studies were selected, the formulas and calculations used in the evaluation, and the conclusions. For information I was provided with copies of an October 22, 1992 letter to Ms. Porter from the Industrial Safety Equipment Association (ISEA) and a December 16, 1992 document with details on ISEA's comments concerning the Working Draft.

Introduction

This document addresses the values of assigned protection factors given to two types of air purifying respirators, i.e., dust/mist (DM) and dust/fume/mist (DFM) respirators. While not discussed in this document, the definitions for these categories of respirators arise from 30 CFR 11, which addresses the certification procedures for respirators as undertaken by NIOSH and MSHA. A respirator must undergo a variety of tests before it can be considered "certified" for use in certain atmospheres.

DM respirators are certified for use in atmospheres where the contaminants carry permissible exposure limits (PEL) greater than 0.05 mg/m^3. The most important aspect of their certification process involves testing the respirator (with the facepiece sealed) for its penetration behavior when challenged with a pure silica aerosol with a count median diameter (CMD) of 0.4-0.6 μm and a GSD less than 2. The 90-min challenge test in an atmosphere of 50-60 mg/m^3 of silica using a steady flow through the respirator of 32 L/min must result in a mass penetration of 1.5 mg or less, which corresponds to an overall mass penetration of 0.87-1.04 %, depending on the upstream silica concentration. These respirators must also undergo a silica mist test for 312 min at a continuous flow of 32 L/min in a concentration of 20-25 mg/m^3 silica mist. No more than 2.5 mg silica dust may penetrate the filter, corresponding to a total silica mass penetration of 1-1.25%, depending on the chamber concentration of silica mist.

DFM respirators must, in addition, undergo a challenge test using a freshly-generated lead fume aerosol and a continuous 32 L/min flow for 312 min. The concentration of lead-oxide fume must be between 15-20 mg/m^3 and less than 1.5 mg lead may penetrate the respirator. This corresponds to a filter mass penetration of 0.75-1.00%, depending on the upstream lead fume concentration. No particle size distribution is specified for this test; fumes generally tend to be quite small with mass median aerodynamic diameters on the order of 0.3-0.4 μm.

DFM filters may be used in atmospheres with a PEL less than 0.05 mg/m^3 or radionuclides if they also pass a DOP challenge test. This involves the challenge of respirator filters (without the respirator) using a DOP (an oil) concentration of 100 μg/L and two continuous flows at 32 and 85 L/min for single filter units (16 and 42.5 L/min for pairs of filters). The tests are carried out for 5-10 secs and must result in a penetration less than 0.03% DOP. When a filter has undergone this test it is often referred to as a HEPA filter, although this term is not employed in the 30 CFR 11 regulations.

Single-use (disposable) DM and DFM respirators for PEL > 0.05 mg/m^3 or DFM respirators for PEL < 0.05 mg/3 (or radionuclides) must undergo these same tests, with one exception. The silica dust test involves the use of a breathing machine for 90 min operated at 24 respirations per minute and 40 L/min, using a 622 kg-m^2/min cam. The exhalation air must be conditioned to 35 C and 94% RH. Penetration must be less than 1.8 mg, corresponding to 0.8-1.0% mass (silica) penetration, depending on the upstream concentration.

It is important to keep the abovementioned information in mind when reviewing recent research on respirator filter behavior. While not discussed in any great detail in the Working Draft, it has been recognized by NIOSH (among others) for at least 10 years that these certification tests may not represent the "state-of-the-art" with respect to respirator performance testing (omitting facepiece fit). In 1981, NIOSH began a project to rewrite and update 30 CFR 11. A review of the regulation identified the following significant shortcomings with respect to the tests for particulate air purifying respirators:

1. they employ time-averaged, rather than instantaneous penetration measurements;
2. they do not consider effects on filter penetration of particle size, face velocity, and aerosol type;
3. they lack sensitivity and are sometimes non-reproducible; and
4. they do not consider effects of temperature and relative humidity on filter penetration.

Moyer (1986) discussed these shortcomings in more detail and outlined the need for their correction:

> "Although the Federal Government has been involved in testing and certification respirators for more than sixty years, the complexity, variety, use and application of respirators have dramatically expanded over the last 15 years. As the uses and applications of these devices have expanded, so has NIOSH's need to assess the adequacy of the application and performance of such devices, and the validity of our testing methodologies....we have recognized the need to propose revisions to the certification regulations (30 CFR 11) to more properly reflect the requirement for appropriate performance in the expanding use environment and to incorporate recent technological advances in testing methodology."

In 1987 NIOSH issued a new proposed regulation, 42 CFR 84, to replace 30 CFR 11. In this new regulation, the Institute outlined changes in its certification procedures for particulate air purifying respirators. It was recognized that certification tests should classify respirators with respect to their filter efficiency, i.e., low (efficiency $\geq 95\%$), medium (efficiency $\geq 99\%$) and high (efficiency $\geq 99.97\%$). Filters would be tested for instantaneous penetration using both a solid and oil liquid aerosol. Prior to testing, filters are conditioned in an environment of 85% RH at 38 C for 24 hr. Two continuous flows (32 and 85 L/min for single filters and 16 and 42.5 L/min for pairs) are used. Both solid and liquid aerosols are neutralized, have an aerodynamic mean diameter of 0.2-0.3 μm and a GSD less than 1.6, and are used at concentrations of 200 mg/m^3. Filter testing is carried out until 100 ± 5 mg of aerosol have contacted the filter (8-16 min for single filters). Instantaneous penetration is monitored and recorded by light scattering photometer or some equivalent instrument throughout the test period and should never exceed the penetration level for the filter category (low, medium, or high).

As discussed by Moyer (1986) the rationale for the use of a "worst case" challenge aerosol is that it will "protect wearers against smaller as well as larger particles." The size range of 0.2-0.3 μm was chosen because it represented the size of maximum penetration for most respirator filters.

Once a respirator (which includes its facepiece and all components such as valves and filters) has been certified it may then be sold with its NIOSH-assigned certification number. Proper selection of the appropriate type of respirator for a particular environment lies with the user (generally, employer), although the manufacturer may play some role in this selection process if consulted by the user. In the selection process the user must consider not only the contaminant and its PEL, but the actual exposure level

in the environment and the fit of the respirator to the employee. It is in this selection process that the application of a "protection factor" comes into play. The "protection factor" represents the degree of protection offered by the respirator to the wearer. However, it is here that there appears to be considerable confusion about "degree of protection" and whether that implies filter behavior, facepiece fit, or both.

In its 1984 Industrial Hygiene Field Operations Manual, OSHA identified a "respirator protection factor" (RPF) value of 10 for particulate-filter, quarter mask or half-mask facepiece respirators if the respirator was fitted using a qualitative fit test (QLFT). If these types of respirators are fitted using a quantitative fit test (QNFT) they may be given a RPF value of no more than 100 for the individual receiving the QNFT. OSHA defines the RPF to be "a measure of the degree of protection provided by a respirator to a respirator wearer. Multiplying the permissible time-weighted average concentration or the permissible ceiling concentration, whichever is applicable, for a toxic substance, or the maximum permissible airborne concentration for a radionuclide, by a protection factor assigned to a respirator gives the maximum use concentration of the hazardous substance for which the respirator can be used. Limitations of filters, cartridges, and canisters used in air-purifying respirators shall be considered in determining protection factors." (Working Draft, p.10) With respect to the last statement, OSHA indicates that "when the respirator is used for protection against airborne particulate matter having a permissible time-weighted average concentration less than 0.05 milligram particulate matter per cubic meter...or for protection against radionuclide particulate matter, the respirator shall be equipped with a high-efficiency filter(s)." While not specifically promulgated as regulation, these statements represent OSHA policy for all substances not regulated in substance-specific standards. This policy was drawn verbatim from the ANSI 1988.2-1980 concensus standard.

As noted in the Working Draft, the ANSI Z88.2-1980 concensus standard was based largely on data generated by Hyatt et al. at Los Alamos Scientific Laboratory (LASL). These studies employed a panel of wearers representing 90-95% of all facial types. Subjects were given respirators (with a variety of filter types) and each individual's protection factor (outside mask concentration divided by inside mask concentration) was determined by measurements in a chamber. These tests evaluated protection factors for full-, half-, and quarter-facepiece respirators with HEPA filters using a relatively monodisperse liquid DOP aerosol with a mass median aerodynamic diameter (MMAD) of 0.46 μm and a geometric standard deviation of 1.4. For single use and quarter mask dust respirators having filters which cannot be changed (and consisting of electrostatic material which can be degraded by DOP) tests employed a NaCl aerosol (MMAD of 0.6 μm).

Tests by Hyatt et al. represent primarily facepiece fit for the respirators with HEPA filters, since these filters will collect 99.97% of the DOP. However, a significant proportion (probably 10-30%) of the NaCl aerosol will penetrate the dust filters, and measurements on the single use and quarter mask dust respirators will represent both filter penetration and facepiece fit. This would account for the assignment of a protection factor of 5 to this latter type of respirator.

It is important to note that the description of the selection process used by OSHA, while based on data generated using a variety of filter types (and thus including both fit and filter behavior), implies that RPFs are primarily related to the **fit** of the respirator, as the decision to use one type of filter over another does not change the value of the RPF. That is, the RPF is assigned to a particular facepiece, regardless of the type of filter (or chemical cartridge) used. It is on this assumption that most subsequent research on respirator protection factors has been based, and in my opinion, it does not appear to be an inappropriate assumption.

The ANSI Z88.2 committee has recently developed an updated standard (1991) indicating assigned protection factors (APF) for a variety of respirator classes. This standard, which is presented in the Working Draft in a slightly changed format (decision criteria with respect to aerosol particle size are incorporated into the APF table in the Working Draft, while in the ANSI document they are found in the list of Selection Steps) gives 1/4 mask, disposable half-mask, and half masks with elastomeric facepieces air purifying respirators an APF of 10. Selection Steps #10, 11, and 12 indicate that thought must be given to the particle size distribution of the aerosol when choosing a filter. If the size is unknown or less than 2 μm (mass median aerodynamic diameter-MMAD) then a high efficiency filter must be used. If the aerosol is a fume either a filter approved for fumes or a HEPA filter must be used. If the size of the aerosol is greater than 2 μm (MMAD) then any filter (DM, DFM, or HEPA) may be used. Again, these recommendations would imply that the protection offered by these types of respirators relies largely on the facepiece and its fit, and not on filter behavior.

Discussion

The Working Draft addresses the issue of facepiece seal in sections 6 and 7, and the issue of filter behavior in sections 8 through 12. However, I believe it is important to consider the latter first, because it affects the appropriate use of the term Assigned Protection Factor. If it can be shown that filter behavior (penetration and collection efficiency) is adequate when the appropriate filter is chosen for a particular aerosol exposure, then it can be concluded that APFs generally reflect the facepiece seal. This is what I intend to demonstrate.

First, however, I would like to make an important point about the use of the word "leakage" to refer to filter behavior. This term is extremely misleading and should be dropped from the document when discussing the penetration of particles through respirator filters. Properly designed and manufactured new filters do not generally "leak." Only filters which are improperly sealed or which develop holes or tears will demonstrate "leakage." Thus, as I discuss the penetration of particles through respirator filters I will use the terms "penetration" to indicate the amount not collected by the respirator, "efficiency" to indicate the amount that is collected by the respirator, and "filter behavior" to include either or both of these terms. Penetration is defined as 1 - efficiency, and efficiency as 1 - penetration. Thus, filter behavior covers either term.

The above discussion, which may seem an unimportant issue of semantics, has great relevance to the evaluation of "filter leakage" as addressed in the Working Draft. The use of the term "leakage" implies that the filter is in some way not behaving correctly. That is entirely false. **Every** filter portrays a certain behavior with respect to penetration of particles through it, and it is a behavior which can be described theoretically. There is, for every filter, a particle size which is not collected as efficiently as (or which demonstrates a higher penetration than) smaller or larger particles. This "most penetrating particle size (MPPS)" as it is often referred to, has been described by a number of researchers in the past 15 years (Thomas and Yoder, 1956; Lee and Liu, 1980; Stafford and Ettinger, 1972; Liu and Lee, 1976), and it has also been shown that the MPPS is dependent on flowrate through the filter. Higher flowrates usually cause a shift in the MPPS to smaller particle sizes. The existence of a MPPS has been shown to occur for every filter--respirator filters included--and its occurrence is a function of the competition between collection mechanisms normally present in every filter. At small particle sizes, diffusion is the primary mechanism by which particles are collected, while at larger particle sizes the mechanisms of impaction and interception are most responsible for collection. This has been well described by Hinds (1982).

In addition, it is possible to predict with a fair amount of accuracy the contribution of each mechanism to particle collection for a particular filter, as well as the overall efficiency of that filter, given certain parameters of the filter. Thus, it is possible to predict the MPPS at a variety of flows for a given filter. The theory used to predict the mechanism-specific collection efficiencies and the total filter collection efficiency is also described by Hinds (1982).

Thus, to reiterate, it would be more accurate if the Working Draft discussed filter penetration or collection efficiency rather than filter "leakage." Filters do not normally leak, but they do have a certain amount of particle

penetration, which is dependent on flowrate, particle size, and a variety of filter parameters. This penetration is normal, expected, and planned for, and can be predicted with some accuracy.

The entire discussion in the Working Draft concerning filter behavior centers on the finding that "substantial filter 'leakage'...occur(s) for contaminant sizes...from about 0.05 to 0.4 μm CMD." (Section 8, p. 61). In other words, the MPPS for DM and DFM filters occurs in this range, and particle penetration at the MPPS has been found to be as high as 30-40% for some DM and DFM filters. The Working Draft treats this information as if it were somehow unexpected and alarming. It is neither of these; rather, such behavior is entirely expected and predictable.

The measurement of filter penetration by the researchers mentioned in this document was for the most part carried out using spherical, monodisperse aerosol particles of near unit density. The measurements evaluated the number of particles upstream and downstream of the filter over a range of particle sizes. Every researcher found the previously-discussed phenomenon of a MPPS, usually in the range of 0.1 to 0.4 μm. Why is it that all of these filters exhibit similar behavior in this size range?

The certification test for DM and DFM respirators utilizes a silica aerosol with a CMD between 0.4 and 0.6 μm and a GSD less than 2. The test requires that a filter must be able to collect 98.96-99.13% of the mass of silica. Since the mass of a particle increases with the cube of its diameter, it is clear that these filters must have excellent collection efficiency for the larger particles in the silica aerosol (i.e., greater than 0.5 μm) and that the collection efficiency of smaller particles can be much lower because their mass contributes so little to the overall mass of all the aerosol that penetrates the filter. Thus, these filters, which must, by the physical phenomenon described earlier, have some size which penetrates to a greater extent than all other diameters, will demonstrate the MPPS in the particle size range where mass contributes little to the penetrating aerosol. If I were asked to design a filter that would pass the NIOSH silica dust test, these are exactly the kind of filtration characteristics I would choose!

The document discusses "narrow-band" and "broad-band" penetration. While these are not common filter or aerosol terms, the phenomena are not unexpected. If designing a filter, as discussed above, one can choose to have relatively high filter penetration over a narrow range of particle sizes or a lower filter penetration of a broader range of particle sizes. Either of these will produce the final goal of less than 1% mass penetration of an aerosol.

If one were to take all of the various measurements of filter penetration made by the four researchers discussed in the Working Draft and apply the silica aerosol size distribution, one would find that predicted mass efficiency

matches or exceeds the silica certification test requirements. In fact, one author demonstrates this point by calculating the range of likely silica mass concentrations inside the respirator facepiece for all respirators tested (Chen 1992). Using these values a range of silica mass penetration could be calculated to be 0.2 to 1% for these filters, well within the requirements of the 30 CFR 11 silica dust test.

The Working Draft suggests that the MPPS may be the most hazardous size for aerosols. However, not all aerosols are equal in their health effects. Some aerosol materials cause essentially "local" effects, i.e., they exert their toxicity within the respiratory system. When "dust diseases" were first described, it was found that those causing pneumoconioses exhibited a strong correlation of disease with mass of material in the lung. In the case of silica, it was further noted that "respirable-sized" particles, i.e., those that penetrated and deposited in the lower gas exchange regions of the lungs, were the most harmful. Thus, we measure a respirable mass to determine silica dust exposures. When the respirator certification tests were developed this was essentially the state-of-the-art with respect to aerosol exposures and health effects. It was not easy to measure particle size distributions and there was only limited capacity to produce monodisperse aerosols. Light scattering photometers were not yet developed. There were no condensation nuclei counters, diffusion mobility analyzers, electrostatic classifiers, or any of the other very sophisticated aerosol measurement instruments which are present today in most well-equipped aerosol labs.

However,while we have made considerable strides in the production and characterization of aerosols both in the laboratory and the industrial environment, we have not made equivalent strides in the understanding of their health effects. It is recognized that for many aerosols there does appear to be a strong relationship between particle size and the "local" effects of the aerosol in the lung. For example, wood dust causes nasal cancer, largely due to the fact that most wood dust is quite large (>10 μm) and thus probably deposits in the nasopharyngeal region of the respiratory system (Hinds 1988). However, there are many non-pneumoconiosis producing aerosols for which the relationship between particle size and health effects is not well-established. Indeed, there may be no such relationship, i.e., any particle landing in the lung may have an equal chance of producing a toxic response.

The Working Draft makes particular mention of lead aerosol as an example of an aerosol which may be absorbed into the blood more readily as a smaller particle size than as larger particle sizes (pp.110-11). However, as discussed by Froines et al (1986) there is little experimental basis on which to draw this conclusion, because there are only limited biological studies concerning uptake of lead from the respiratory system. It is too early, at this point, to conclude that lead will be more harmful in smaller particle sizes.

There are many aerosols with health effects which may be related to size, but for which there are few data to establish the relationship between disease and particle-size related exposure. Thus, it is inappropriate and mistaken at this time to conclude that any one particle size is more harmful than another for all aerosols. We must give the field of aerosol epidemiology a chance to determine this relationship before determining that the MPPS demonstrated by DM and DFM respirators occurs in a range representing severe hazards to respirator wearers.

In fact, it is unlikely that particle size distributions will center on that most penetrating particle size range in the industrial environment, except perhaps where newly-generated fume aerosols occur. The ANSI Z88.2-1991 selection steps requiring the evaluation of particle size distribution (based either on professional judgment or actual measurement) attempt to address this issue as it relates to the selection of the appropriate filter type. Rather than selecting a filter based on the exposure limit (which is no longer appropriate), ANSI Z88.2 1991 addresses selection on the basis of aerosol size. This is more appropriate given what is known about filter behavior for a range of sizes, as well as what can be guessed or measured about an aerosol in a particular environment. With the advent of personal cascade impactors, measurement of particle size distribution has become much easier than in the past, and will become more routine as we begin to attempt to correlate particle size with specific health effects. The ANSI selection steps represent state-of-the-art in aerosol measurements which are neither difficult nor overly expensive to perform.

Therefore, it is possible to select a respirator filter which will demonstrate very little penetration in the particle size range of interest, ensuring that the respirator's APF will be primarily affected by facepiece fit. It is on the basis of this assumption that recent measurements of protection factors have been made, and it appears an adequate assumption given the present knowledge of aerosol measurement and filter behavior. If NIOSH has concluded that filter penetration is too high for some filters in some size range, then it is their duty to change the certification tests such that filters demonstrating such penetration will not be placed on the market. It appears somewhat backward to lower the APF for DM and DFM respirators because their filters exhibit penetration behavior which has not been tested for in the present certification tests. I recommend that the 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.

It is now important to turn to the discussion of determining APFs on the basis of facepiece seal. The Working Draft labels all studies since those of

Hyatt as critically flawed, because they involve subjects who have been fit tested. I do not believe this is a serious drawback to these studies, because fit testing is a procedure required of all respirator users. Whether employers perform such fit testing should have little bearing on APFs.

In fact, the argument that most elements of a respirator program are not adequately pursued by most employers has little or no bearing on the fit that could be achieved if these elements were implemented. The proper implementation of a respirator program relies on enforcement. Just as we perform car crashes with mannequins wearing seat belts--although a large percentage of people do not wear their seat belts--we cannot hope to evaluate facepiece leakage when a respirator is not adequately fitted. Rather, we must either design respirators (or seat belts) which can only be worn correctly or we must rely on proper enforcement of 29 CFR 1910.134 to ensure they are worn and fitted properly. While generally accepted by the industrial hygiene community that respiratory protection is the control of last resort, there remain today many industrial situations where it is the only feasible means of controlling worker exposures. Thus, we must enhance the enforcement of respiratory protection regulations and policies to ensure that properly selected respirators are worn correctly in the workplace.

It is true, on the other hand, that very little correlation has been found between an individual's laboratory fit test value (QLFT or QNFT) and the workplace protection factor measured for the same respirator. This lack of correlation has not been adequately explained to date. It could result from the differences in the length of tests and the lack of work simulation in the laboratory tests. It could also result from problems encountered in measuring from inside a facepiece in either setting. At this point in time, it is generally thought that workplace measurements of facepiece leakage are more "representative" of the true performance of a respirator, despite all the problems with making such measurements.

ISEA has expressed considerable dismay with NIOSH's decision to exclude a large number of workplace studies from its evaluation of WPFs. Since I have not been given the chance to review these studies I cannot judge whether the decision to exclude them was appropriate. Therefore, I would suggest that NIOSH list every such study presently available (published and unpublished) and its reasons for accepting or excluding a particular study. At this point, the exclusion of some studies without explanation appears unscientific and arbitrary.

Several criteria are outlined in the Working Draft by which a WPF study was considered "acceptable." Each of the three criteria chosen does have some significance with respect to the measurement of a protection factor, but there are other criteria which may be just as important. In addition, the determination of how failure to meet each criteria will affect final protection

factor estimates is not necessarily as one-sided as is suggested in the Working Draft.

The first criterium, the use of a NIOSH deep-probe, arises from work done by Myers et al (1986, 1988). Using an acetone vapor, it was found that sampling with a probe flush to the facepiece (the common practice in fit testing) could introduce significant errors in the measurement of in-facepiece concentration. However, it was found that the use of this type of probe could introduce both positive and negative biases, depending on the respirator. It was also found that the "best" sampling method involved a deep probe located near the mouth with a sample drawn only during exhalation. While it is not possible to sample during exhalation at present, the deep probe has been recommended for in-facepiece sampling.

However, it should be kept in mind that this research used a vapor. When an aerosol exposure is being evaluated, other types of errors may be possible. Experimental work by Liu et al. (1984) evaluated biases with respect to probe entry efficiencies, demonstrating that probe design may play a significant role in sampling efficiencies inside a respirator facepiece. No work, however, has combined that of Myers on probe depth with that of Liu on probe design to evaluate biases with respect to particle size, respirator design, and flowrate. Thus, it is not necessarily appropriate to assume that probe depth will play a similar role in sampling efficiency for aerosols as has been shown for vapors. It should be noted , however, that four of the WPF studies evaluated in the Working Draft (#4, 5, 6 and 7) did use the probe design found by Liu to show the least amount of loss during in-facepiece particle sampling.

Filter holder wall deposition is a phenomenon which has been found in only a limited number of studies with a few aerosols. It has not been determined that this phenomenon occurs for all filter cassette sampling. In fact, the charge on the aerosol probably plays a strong role in such deposition. Many aerosols do not carry a significant charge. Thus, it is not correct to assume that such bias will exist for all WPF studies.

There are probably other important criteria one might consider when evaluating a WPF study. It would be more appropriate for NIOSH to develop a list of such criteria for future studies, in order to improve the faults found in studies to date.

I am not convinced by the arguments presented in this document that the APF for half-facepiece respirators with DM or DFM filters should be lowered. The evaluation is not thorough with respect to its selection of research studies, nor are the criteria used to assign bias adequately addressed. Based on these points, I must withhold my judgment on whether

the conclusions drawn concerning the lowering of APFs on the basis of fit are valid.

Summary

I would like to summarize the points I have made in my discussion above.

1. The discussion of filter "leakage" reflects a misunderstanding of the significance of the results of the studies reviewed. These studies demonstrate that respirator filters show a behavior similar to that of other types of filters, with a most penetrating particle size dependent on flowrate. Because the studies measure count or number penetration they do not adequately reflect the behavior of a filter when it is evaluated for the penetration of the mass of an aerosol, which for many aerosols is the more relevant measure of health effects.

2. Filters tested in these studies will easily pass the NIOSH certification tests for silica dust, silica mist, and lead fume (for DFM filters) as outlined in 30 CFR 11. These are all tests of mass penetration.

3. Rather than penalize DM and DFM filters for behaving as they have been designed with respect to the present 30 CFR 11 certification tests, it would be more appropriate to propose new certification tests. NIOSH has already done this in 1987 with 42 CFR 84. This proposed regulation should be promulgated.

4. APFs primarily reflect the faceseal or fit of a respirator. Selection criteria and certification tests will ensure that filters perform adequately if they are chosen correctly. There is no reason to believe that users will be unable to choose the appropriate type of filter for a respirator on the basis of aerosol type and particle size distribution.

5. Given the above points there is no reason to lower APFs of half or 1/4 mask or single use air purifying respirators with DM or DFM filters. Filter penetration does not play a significant role with respect to the protection factor of these respirators.

6. Criticism of workplace protection factor studies on the basis of their use of fit tested subjects is not appropriate and should be deleted. It is accepted practice in the respiratory protection field, based on regulation and professional practice, that wearers must be fit tested prior to wearing a respirator. Whether this actually occurs should have little bearing on this particular evaluation.

7. It is difficult to evaluate NIOSH decisions with respect to WPF studies because many such studies appear to have been eliminated without any

explanation for this decision. NIOSH should discuss its criteria for accepting and rejecting all such studies before beginning its evaluation.

8. The criteria used to evaluate "accepted" WPF studies are, at best, quite limited. In some cases they are incorrect with respect to assignment of bias. A more thorough discussion of all such biases and the criteria for a "good" WPF study would be more useful at this time. With the development of good study design criteria, better studies will be performed. This should be the goal of NIOSH at this time, rather than a critique of those studies done to date.

9. Given the above points, the evidence is not strong enough to support the lowering of the APFs on the basis of facepiece leakage.

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