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January 28, 2005

(Names and signatures have been removed in order to protect the privacy of the individuals submitting the complaint.)

CERTIFIED MAIL

Mr. Frank Frodyma
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Av. NW
Washington, DC 20210

Dear Mr. Frodyma:

Subject: Information correction request

The DOL web site indicates that you are the OSHA designee for accepting correction request under the provisions of the Data Quality Act. I'm requesting your Agency make corrections for the information used to develop the proposed standard on Respirator Assigned Protection Factors (Docket H-049C).

Rationales for this request are enclosed. Please contact me at 410-721-3468 if you have any questions.

Thank you for your consideration.

Sincerely,

(Name removed)

Enclosure

Correction Request Under the Provisions of the Data Quality Act Regarding the OSHA APF Proposal (Docket No. H-049C)

Under the provisions of the Data Quality Act, I request that the Occupational Safety and Health Administration (OSHA) reconsider the assigned protection factor for filtering facepieces that is a part of the proposed rulemaking of Assigned Protection Factors (APF) (OSHA Docket H-049C) because the studies selected by OSHA to support the proposed APF for the filtering facepiece fails to meet the quality criteria established under the Data Quality Act.

The October 2002 Department of Labor (DOL) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor states that the information used for rulemaking meets the objectives of "utility," "objectivity," and "integrity." The information be objective - "accurate, reliable, and unbiased, and presented in accurate, clear, complete and unbiased manner." Also, the selected data must also meet the standards specified in the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b) (3) (A) & (B)). OSHA has not followed these guidelines in developing the assigned protection factor (APF) for the filtering facepieces in the proposed standard on Assigned Protection Factors (Docket H-049C). Rationales for this request follow:

A. Background Information

The term "assigned protection factor" (APF) is the ratio between the ambient concentration and the OSHA enforced air contaminant permissible exposure limit (PEL) for properly trained and fit tested respirator wearers. It is a measure of the level of protection provided by a respirator. Three types of data have been used to assign respirator protection factors: quantitative fit testing (QNFT), simulated workplace testing, and workplace testing. The QNFT is performed when the test subject performs static exercises that simulate workplace movements inside a test atmosphere. Under simulated workplace testing, the test subject performs a variety of body movement exercises that simulate the worker movements inside a controlled environment test chamber. In workplace protection factor (WPF) testing, the test is performed at a work site selected by the test conductor.

The two federal agencies are establishing the APFs for respirators are the National Institute for Occupational Safety and Health Administration (NIOSH) and OSHA. NIOSH is responsible for testing and certifying respirators used by industries under OSHA's jurisdiction. In the early 1970s, NIOSH adopted the protection factors developed by the Los Alamos Scientific Laboratory (LASL)[1] as the respirator APFs. These values are based on QNFT and they are listed in the NIOSH document, Respirator Decision Logic (RDL). OSHA has also adopted these APFs in the Agency promulgated health standards. In the early 1980s, after receiving respirator user complaints, NIOSH staff conducted workplace testing of certified powered air-purifying respirators (PAPRs). They found that these respirators did not achieve the APF as prescribed in the RDL. Based on the test results, the Agency revised the RDL. OSHA has accepted independent simulated workplace studies to modify Agency enforced APFs.

In 1987, NIOSH proposed a revision of the respirator test and certification regulations (42 CFR 84). It proposed that respirators only be certified after achieving a required workplace protection factor (WPF) in workplace testing. Respirator manufacturers and other parties opposed this requirement. In 1991, NIOSH sponsored a public meeting to address this issue. The three-day technical conference addressed many problems and deficiencies associated with workplace testing. It concluded that since there is no standardized test protocol to conduct workplace testing, this allows manufacturers shop around for a workplace that will provide test conditions that are favorable to their products. Field testing would introduce uncontrollable test conditions, a high level of uncertainty, and a large number of poorly defined variables. The accuracy and reproducibility needed for a valid certification test would not be currently achievable. Simulated workplace protection factor study would be the choice for respirator certification (refer to Appendix I for more detailed discussions on this subject). As a result of this conference, NIOSH has abandoned the concept of using WPF studies for respirator certification. OSHA participated in the NIOSH conference and is fully aware of the deficiencies associated with workplace testing and NIOSH's decision of not using workplace data for rulemaking.

B. OSHA Record on the Performance Deficiency of Filtering Facepeices

The OSHA record regarding respiratory protection indicates that the Agency has no confidence in the performance of filtering facepieces. OSHA's position can be found in the revised asbestos and cotton dust standards.

Asbestos Standard

The revised OSHA asbestos standard prohibits the use of the filtering facepiece (disposable or single use respirator). One filtering facepiece manufacturer petitioned OSHA to allow the use of filtering facepiece. OSHA rejected the petition and made the following comments:

"*On the contrary, 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. . . . There is no acceptable method for verifying their (disposable respirators) fit. . . .The record clearly shows that, as a class, disposable respirators do not provide a reliable face fit after initial fit testing. . . They can not 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. . . . Workers unanimously opposed use of disposable respirators, Workers stated that disposable respirators do not fit well, . . .and failed to provide a good face seal.*"[2]

Cotton Dust Standard

The revised OSHA cotton dust standard assigned the filtering facepiece with an APF of 5 and the elastomeric facepiece respirator with an APF of 10. One filtering facepiece manufacturer petitioned OSHA to raise the APF using the verification data on the required positive pressure fit check (PPFC or user seal test) as the supporting documentation. After reviewing the test data, OSHA rejected the petition and made the following comments: '

". . . This means that as many as 41 per 100 improperly fitted wearers of 3M's 8710 respirator could be erroneously passed by 3M's positive pressure fit check (PPFC) procedure. As with the previous analysis, this data does not provide strong laboratory evidence that 3M's PPFC is effective to allow a protection factor of ten for the 8710 respirator."[3]

The U.S. Court of Appeals agreed with OSHA when the manufacturer petitioned the Court for a review. The Court denied the petition and ruled that *"the Positive Pressure Fit Check is effective for daily checking of the fit of elastomeric facepieces because the air intake to the valves can be easily blocked by the hands. For disposable respirator, the entire filter surface is intended to permit air intake. The worker's hands cannot effectively block intended air intake, and the intake only, while leaving unobstructed air taken in because of the respirator's improper fit."*[4]

OSHA's record indicates that filtering facepiece is inferior to the elastomeric facepiece respirator in providing worker protection. In 1995, NIOSH revised the testing regulation for certifying particulate filtering respirators (42 CFR 84) so that filters are challenged with submicrometer test aerosol at a much higher airflow rate. The filtering facepieces approved under the new testing regulations vary very little in shape and fit from the devices approved under the old regulation (30 CFR 11). These performance deficiencies still apply to the currently approved filtering facepieces.

OSHA Solicited Information on Workplace Testing

When OSHA proposed a revision of the standard on Respiratory Protection (29 CFR 1910.134), in 1994, the Agency left the APF under a separate rulemaking. OSHA solicited comments regarding a Nicas study that proposed a method of statistical analysis of workplace data. Organization Resource Counselors Worldwide, Inc. (ORC), a consulting company for major U.S. corporations, and 3M Company, a major sponsor for the OSHA selected workplace protection factor studies, have submitted comments on using WPF studies for protection factor assignment. They stated that the studies are flawed and obsolete. Also, there is a lack of valid data and available data were too variable (Ex.1-182-5, Ex. 1-182-10, Ex. 10-26) (a more detailed discussion appeared in Appendix II).

C. Deficiency in Objectivity and Integrity

OSHA Relies on Non Peer-Reviewed Studies for Rulemaking

OSHA always relies on independent studies to ensure data objectivity and integrity when developing standards and changing compliance policies. The acceptance of the PortaCount as a fit testing instrument and raising the APF for the loose fitting hood and PAPRs are examples. In the APF proposal, OSHA did not conduct any independent studies to support the APF for the filtering facepieces. Among studies selected by OSHA to support the proposed APF for the filtering facepieces, a majority of selected studies are non peer-reviewed and are performed or sponsored by a single filtering facepiece manufacturer.

The DOL Data Quality Guidelines require that data used for rulemaking be objective and have integrity. Instead of using independent studies for the rulemaking, OSHA ignored the issues of data integrity and conflict of interest in selecting flawed non peer-reviewed WPF studies conducted or sponsored by the filtering facepiece manufacturer who has a vested interest in raising the APF of the filtering facepiece.

Limited Utility of Test Data

The respirators used in studies selected to support the proposed filtering facepiece APF of 10 are not representative of the total population of filtering facepieces. Filtering facepieces come in a variety of shapes, such as formed cup, flat, half fold, pleated, accordion folds, and with or without an exhalation valve. Only a small fraction of the formed cup shape filtering facepieces from only very few manufacturers have been tested in the workplace. Therefore, there is no information on how well the other untested filtering facepieces models will function in the American workplace.

Using Obsolete Data for Rulemaking

The OSHA selected filtering facepiece WPF studies for the APF proposal is generally old, and may lead to incomplete and misleading conclusions for the filtering facepiece APF. The data almost exclusively reflects the old 30 CFR 11 approved respirators that are no longer approved and available.

Performance Advantage of Elastomeric Half-Mask

The superior performance of the elastomeric half-mask has been recognized by many respirator users and professionals. The elastomeric half-mask respirator provides a better face seal than filtering facepieces, since most elastomeric half-mask respirators are made of more pliable silicone rubber that provides a much better seal on the face. In addition, elastomeric half-mask respirators are made in three sizes and have adjustable head straps and a head cradle to improve stability while the majority of filtering facepieces are made of less pliable fabric and one or two sizes. Also, the head straps are non-adjustable. However, filtering facepieces with an adjustable nose piece band cannot obtain repeatable fit factors. The better fitting elastomeric half-mask provides better performance in the workplace than the filtering facepiece.

D. Data Deficiency on OSHA's APF Proposal

Failure of Meeting the Concentration Requirements

The filtering facepiece is assigned with an APF of 10. This means that the device would provide protection at the concentration up to 10 times the OSHA permissible exposure limit (PEL) for the air contaminant in question. In workplace testing, the ambient concentration is expressed as the geometric mean concentration. In order to demonstrate that the filtering facepiece should be

assigned an APF of 10, it should be tested at a workplace that has an ambient geometric mean concentration of at least 10 times the OSHA PEL for the air contaminant. However, very few of OSHA selected studies meet this requirement. In some studies, the ambient concentrations are lower than the OSHA PEL where respirator use is not even required (Study 16, Ex. 1-64-34; study 14, Ex. 1-64-15). There is no peer-reviewed study to indicate that a respirator tested at low ambient concentrations would provide the same performance when tested at 10 times OSHA PEL concentration.

Uncertain Quality of Selected WPF Studies

OSHA's definition for APF states that the employer must have an effective program in order to apply the protection factor specified for each type of respirator. This means that the test site where the WPF study was conducted must have a continuing effective respirator program. However, OSHA has not obtained the site respiratory protection program to verify whether the sites for selected studies have effective program in place. At the OSHA APF hearing, one participant testified that many test subjects in one OSHA selected WPF study failed the required fit test[5] (Ex. 16-23-1-42). Without a site respiratory protection program for review, there is no assurance that the test site has an effective respiratory program.

Non-Representative Test Sites

In order to apply the test results of one WPF study to other workplaces, the test conditions must be representative of other workplaces. Many test sites chosen for these studies were selected solely on the basis of availability. Moreover, key study attributes such as hot and humid conditions, long work hours, and heavy workload are the exception, not the norm for most of the cited studies. This creates tests that lack objectivity.

Lack of Standardized Test Protocol

A standardized test method would ensure the quality, objectivity and reproducibility of the data. WPF studies were performed as early as the mid 1980s. During the OSHA APF hearing, Dr. James Johnson, Chair of the ANSI Z88 Committee which develops respiratory protection standards, testified that no one has ever approached him to develop a standardized workplace protection factor testing protocol (Ex.16-23-2-176). Without a standardized testing protocol, the test conductors are shopping for a test site that would yield favorable test results.

Non peer-reviewed studies

The DOL Data Quality Guidelines requires that peer-reviewed science and supporting studies must be conducted in accordance with sound and objective scientific practices for rulemaking. OSHA selected a majority of non-published and non peer-reviewed WPF studies to supporting the proposed APF for the filtering facepiece. There are major data bias and deficiencies on these studies. One instance is a non peer-reviewed WPF study on asbestos removal (Study 2, Ex. 1-64-54) using the accepted analytical method developed by NIOSH which requires that fiber

counting stops at 100 fields or 100 fibers. Since very few fibers were found in the in-mask samples, the counting field has been increased from 100 to 500 in order to search for fibers. This increased counting fields artificially boosted the WPF values. A sample reports a WPF of 7,800. However, only one fiber was found in the in-mask sample. If one more fiber was found, than the WPF would be reduced to 3,900. OSHA did not review the raw data but accepted this study for performing statistical analysis. The test data also demonstrated that the negative pressure filtering facepiece provides better protection that the positive pressure self-contained breathing apparatus (SCBA) that is used for fire fighting and rescue operations.

Another study measured airborne metal dust in metal grounding operation (Ex. 1-64-34). Since the ambient contaminant concentration in this work environment is much lower the OSHA PEL, a respirator is not required in this operation. There is no respiratory protection program at this test site.

In order to ensure the quality of selected non peer-reviewed studies, OSHA should form an independent panel to establish criteria and conduct a comprehensive review to select studies for statistical analysis. However, OSHA has not conducted an independent review to determine if the selected studies are qualified for statistical analysis.

Over Estimating WPF values

Particle size has a significant effect on WPF values. Using the studies listed in the OSHA APF preamble as an example (FR 68-34095, June 6, 2003), the same respirator made by three manufacturers was selected for three studies: a foundry (Study 7, Ex. 1-64-51), a steel mill (Study 8, Ex.3-14), and a spray painting operation (Study 9, Ex. 1-64-52). The measured geometric mean WPFs follow:

Respirator	Foundry	Steel Mill	Spray Painting
AO	98	280	2,211
MSA	163	427	4,580
Scott	94	252	6,630

The particle size at the foundry is smallest compared to the large paint sprays. It is obvious that a much higher WPF can be achieved when a work site with large particles is selected. To reduce the particle size bias, the WPF should be corrected for particle size variations. However, OSHA has not made any corrections for the selected studies.

Probe Bias

NIOSH studies indicate that there is a significant facepiece probe bias when collecting in-mask samples in WPF studies. The least biased sampling location is the midline between the nose and mouth. NIOSH has published peer-reviewed studies to determine the probe bias of many approved elastomeric half-masks[6]. A correction factor can be calculated for probe bias.

However, there is no study to measure the probe bias of various configurations of filtering facepieces. In several OSHA accepted studies, the probe is located on the side of the filtering facepiece (Study 15, Ex. 1-64-16, and Study 7, Ex-1-64-51). This location introduces significant error. OSHA is aware of the probe bias problem but still accepted these studies.

Worker Bias

There are three types of WPF studies. The NIOSH conducted or sponsored studies; the employer conducted or sponsored studies; and the respirator manufacturer sponsored or conducted studies.

Using the similar respirator, the NIOSH study reports a 5th percentile WPF of 3 (Ex. 1-64-61); the employer conducted study shows a WPF of 7.5 (Ex. 1-64-70); and the respirator manufacturer conducted study reports a WPF of 32 (1-64-34).

Test subject monitoring is the major source of significant difference in achieving WPFs. In the respirator manufacturer conducted study, workers were constantly monitored. In some studies, each worker was observed by one monitor. However, workers are less well monitored in the NIOSH and employer studies. When the worker is constantly monitored, he or she would pay extra attention in performing the assigned duties and a high WPF is achieved. However, this artificially high WPF value is an unrealistic value that cannot be reproduced at an unmonitored test site. However, OSHA has ignored the fact of worker bias.

Lack of Comparison Studies

When a study-by-study comparison between the filtering facepiece and the half-mask is performed, the peer-reviewed filtering facepiece studies show lower protection than the elastomeric half-mask studies (FR 68-34095, June 6, 2003). Some studies demonstrate that the filtering facepiece cannot achieve a commonly used 5th percentile APF of 10 (Ex. 1-64-61, Ex. 1-64-70 and Ex-1-64-11). In a non peer-reviewed study, the filtering facepiece performed equal to or better than the elastomeric half-mask with the 5th percentile WPF in excess of 10 (Ex. 1-64-54).

The 1991 NIOSH Technical Conference on workplace testing concluded that due to uncontrollable test conditions, the validity of extrapolating the results of any study to general use situations is in question. Also, the validity of extrapolating test results between different work situations is in question. Since all test attributes such as ambient concentration, particle size, work rate, work duration, sampling and analytical methods vary, it is inappropriate to perform statistical analysis on data collected from different test conditions.

It appears that OSHA has selected more non peer-reviewed WPF studies than peer-reviewed filtering facepiece studies to perform statistical analysis. The higher WPF values of non peer-reviewed studies tend to support the statistical analysis to conclude that there is no difference in performance between filtering facepieces and elastomeric half-masks. The foregoing

discussions have demonstrated the performance deficiencies associated with filtering facepieces. Also, there is no assurance on the quality of OSHA selected non peer-reviewed studies. Since all test attributes vary from work site to work site, it is inappropriate to lump vastly different studies together for performing statistical analysis. The only meaningful way to support OSHA's proposal that there is no performance difference between filtering facepieces and elastomeric half-masks is to conduct a side-by-side study using various configurations of filtering facepieces and elastomeric half-masks under stressful controlled test conditions. The test protocol in the OSHA sponsored Los Alamos National Laboratory conducted simulated workplace protection factor study should be selected for this testing (Ex. 1-64-101)[7]. OSHA has conducted numerous independent studies to support standard development and to set compliance policy activities. OSHA should conduct such a study to correct the data quality deficiencies of filtering facepieces in this rulemaking.

Dr. Kenneth Brown, the contractor who performed the statistical analysis of OSHA selected studies also recognizes the deficiencies of OSHA selected WPF studies. He concluded in his report that "WPF has limitation as a measure of respirator effectiveness, because of the Co (ambient concentration) effect, and that workplace studies have limitations for comparison of respirator performance because of uncontrolled sources of variability. Improved guidelines for workplace studies are needed to reduce variability and improve comparability across studies, although the heterogeneity of workplace environments would remain a limitation. Chamber studies, or some other assessment methodology with experimental controls, are needed for a baseline test and comparison of respirators" (Ex. 5-1).

Conclusions

The DOL Data Quality Guidelines require that the information used for rulemaking meet the objectives of objectivity, utility, integrity, and presented in accurate, reliable, clear, complete, and unbiased manner. Also, peer-reviewed studies be selected for rulemaking. OSHA is aware of the performance deficiencies of the filtering facepiece and the bias of workplaces studies, however, OSHA still selected a majority of non-peer reviewed and flawed WPF studies for assigning the proposed APF for the filtering facepiece. Also, the selected studies failed to meet the quality, objectivity, utility, and integrity objectives established by the DOL.

Request

OSHA should conduct a side-by-side simulated workplace protection factor study by selecting various configurations of filtering facepieces and elastomeric half-masks using the Los Alamos simulated workplace protection factor test protocol. Also, OSHA should remove the deficient filtering facepiece WPF studies from the APF Docket (H-049C).

Appendix I - NIOSH WPF Conference.

In 1987, NIOSH proposed a revision of its respirator certification regulations (from 30 CFR 11 to 42 CFR 84). To ensure that approved respirators provide adequate field performance,

NIOSH proposed that workplace testing would be a part of the revised respirator testing and certification program in 1987. The test respirator must meet a specific performance level (protection factor). Respirator manufacturers and other parties opposed this requirement. In 1991, NIOSH sponsored a public meeting to address this issue[8]. There were more disagreements than agreements as to how to conduct a WPF study.

Some of the major technical points and problems discussed during the presentations including the following:

- Test protocols are different in most cases; environmental conditions are poorly defined; the number of test subjects and usable data is limited for any single study; particle size information is not always measured; even through particle size and contaminant concentration seem to influence the measured WPF. This raises questions regarding the interpretation of any single study and the comparison of different studies.

- There has been no evaluation of the effect of worker response to being monitored. This raised questions regarding the validity of extrapolating the results of a single study to a general use situation.

The validity of extrapolating test results between different work situations is in question.

There is no well-defined methodology for evaluating gas/vapor situations.

One presenter, a representative from a major respirator manufacturer who has conducted many WPF studies, made the following remarks:

"*I would say that we do not know what these results mean. All we are doing now is working on methodology and doing research. We do not know what the test results really mean. So in conclusion, workplace protection factor studies we think can be useful in evaluating performance of respirators in the workplace. But the accuracy and reproducibility needed for a valid certification test is not currently achievable in this type of testing. Whether or not it will ever be achievable is a question you might ask. I would think for what we know the chances are it will not be achievable. It is not possible for us to standardize test protocols, to standardize sample collection, sample analysis, data analyses, data interpretation in the manner that would adequately address unresolved technical issues.*"

NIOSH also requested two consultants, Harry Ettinger and William Hinds, to critique the conference. Ettinger made the following statements in his report[9]

"Based on these technical problems the overwhelming opinion of meeting attendees was negative regarding the use of field testing as part of the certification process." They believed that:

a) *It was not possible to identify a representative workplace.*

b) *There was no standard test protocol.*
c) *Field testing would introduce uncontrollable test conditions; a high level of uncertainty; and a large number of poorly defined variables.*
d) *There was insufficient information to implement a test procedure of this type into a formal certification program.*
e) *Field testing to determine WPF was in a research stage of development."*
f) *The validity of extrapolating the results of any study to general use situations is in question.*
g) *The validity of extrapolating test results between different work situations is in question.*

Hinds made the following statements in his report[10]:

"There is great intrinsic variability in the measurement of WPFs because of the nature of the quantities being measured. This variability exists in addition to the variability of the quantity being measured, namely respirator performance, which is primarily associated with filter penetration and facial seal leakage. The source of contaminant in the workplace is variable with time and will often depend on quantities such as, production rate, process temperature and pressure. Airborne concentrations are intrinsically variable because they depend on air motion, air mixing, and worker movement in a complex and currently unknown way. There is substantial variation in the performance of aerosol filters even between filters from the same lot from the same manufacturer. Finally there is the human variability. People breathe differently, move differently, and generally behave differently while doing same job. These and other factors result in WPFs having a broad lognormal or other non-normal distribution, which complicates the statistical analysis of these data."

"Much of the variability cited above for workplace testing can be reduced by simulated workplace testing under controlled and reproducible conditions. In simulated workplace testing it is relatively easy to maintain test agent concentration (and size distribution in the case of a test aerosol) constant over time and uniform throughout the test chamber. Test subject's tasks and motion can be standardized."

"To conduct meaningful workplace testing of respirators, testing needs to be standardized. This provides a level playing field for all manufacturers and allows the regulator and the user to interpret the results and make comparisons. Standardized tests would prevent manufacturers from shopping around for a workplace that will provide test conditions that are favorable to their product. These needs are best met by controlled and reproducible simulated workplace testing."

"The nature of workplace testing of respirators is such, that for a given respirator, tests would likely be conducted in one or a very few workplaces. This is a serious limitation because of the difficulty generalizing performance results from one or a few workplaces to the broad range of respirator applications. At some level each workplace is different. They have different sources,

environmental conditions, work practices, and different chemical and physical characteristics of the airborne contaminants."

Based on opinions of overwhelming majority of attendees of the conference, NIOSH decided that workplace testing would not be a part of respirator certification program. At the OSHA APF hearing, the NIOSH panel stated that simulated workplace testing would be a part of inward leaking testing for respirator certification.

Appendix II - Data Deficiencies

The Organization Resource Counselors, Inc. (ORC) and 3M Company, a major sponsor for the workplace protection factor studies, have submitted comments on using WPF studies for protection factor assignment. ORC states that "*The use of existing, often flawed workplace protection factor studies is not a solution to the problem. . . . A reliance on sophisticated statistics is an attempt to compensate for lack of reliable scientific data on respirator performance is both bad science and bad policy* " (Ex. 1-182-10). 3M states: "*Insufficient valid data were available for such an evaluation, and that the data were available were too variable.*" (Ex.1-182-5).

Below is a quote from ORC Worldwide that appeared on OSHA Docket H049C, Exhibit No: 10- 26: "... *There is a profound lack of data on respirator performance over the years, such that what little there is provides but a small glimpse of the universe of respiratory protection, In addition, the existing data are obsolete, some having been collected as long as 20 years ago. There is clearly a need for an ongoing effort to collect relevant, current data on respirator performance. . .* "

ORC Worldwide also made the following comment in the OSHA Informal Public Hearing that appeared in Docket H049C, Exhibit No.16-11: ". . . *unfortunately there has been a profound lack of comprehensive research data on respirator performance over the years, such that what little there is provides an incomplete glimpse of the universe of respiratory protection. In addition, much of the existing data may not represent the current state of respirator performance, some having been collected as long as 20 years ago . . .* "

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