

LAO Consulting, Inc.
Industrial Hygiene
1855 West Queens Ct.
Crofton, MD 21114
410-721-3468

OSHA CORRESPONDENCE
CONTROL UNIT

2005 MAY 31 P 3: 56

May 26, 2005

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

CERTIFIED MAIL

The Honorable Jonathan Snare
Acting Assistant Secretary
U.S. Occupational Safety and Health Administration
200 Constitution Ave NW
Room S-2315
Washington, D.C. 20210

Dear Mr. Snare:

Subject: Appeal

I'm filing an appeal to your decision for denying my information correction request under the provisions of the Data Quality Act.

On January 28, 2005, I filed a request to correct the information used to develop the proposed standard on Respirator Assigned Protection Factors (Docket H-049C) under the provisions of the Data Quality Act. Your letter of April 15, 2005 denied my request. It states that "*After reviewing your letter, we note that the information provided is already contained in the APF Docket (H-049C). OSHA is presently developing a final rule for assigned protection factors. The final rule will be based on the information in the record. Therefore, OSHA has determined that at this stage of the rulemaking, corrections to the information used to develop the proposed standard are not warranted and your request is denied.*" On April 26, 2005, I contacted Mr. Frank Frodyma, the Agency contact person on Data Quality Act inquiries, regarding filing an appeal to your decision. On May 10, 2005, Mr. Frodyma responded that I should file my appeal with you (copy of e-mail message enclosed).

The Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor states that the information should be "objective, accurate, reliable, and unbiased," and presented "in an accurate, clear, complete, and unbiased manner." Also, Appendix II: Adapting the Principles under the 1996 Safe Drinking Water Act Amendments for Safety and Health Risk Analyses states that "DOL is adapting the principles of the Safe Drinking Water Act Amendments for both health and safety risk analyses. For health analyses, the principles will be adapted as follows:

“1. In taking agency actions that are based on the use of science in the analysis of health risks, the agency shall use

- a. the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.
- b. data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data), including:
 - i. exposure data such as that generated by enforcement activity, contained in published literature, and submitted to the rulemaking record; and
 - ii. testimony and comment from experts familiar with the underlying scientific information related to the risk analysis and other relevant information in the rulemaking record.”

The DOL Data Quality Act Guidelines was published on October 1, 2002 and the OSHA APF proposal was published on June 6, 2003. Within that eight months time period, OSHA has had sufficient time to comply with the DOL guidelines for developing the proposed rule on the Assigned Protection Factors (APF). However, OSHA selected many non-published and non peer-reviewed workplace protection factor studies to perform statistical analysis. Based on these non peer-reviewed studies, OSHA assigned the filtering facepiece (disposable respirator) with the same assigned protection factor as the elastomeric facepiece.

OSHA has a long held the position that the filtering facepiece does not provide the same level of protection as the elastomeric facepiece respirators. Two Republican appointed acting Assistant Secretaries for OSHA, Mr. Frank White and Mr. Patrick Tyson, made public statements on this issue. Mr. White stated that *“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.”*¹

Mr. Tyson had stated that a satisfactory facepiece fit check (user seal test) cannot be performed on the filtering facepiece. He stated that *“. . . 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.”*² The U.S. Court of Appeals has ruled on this issue and agreed with OSHA’s position³. OSHA has recognized the inferior performance of the filtering facepiece. However, OSHA still treated these two classes of respirators as equal in the APF proposal.

OSHA selected many non peer-reviewed workplace protection factor (WPF) studies conducted by one respirator manufacturer. In 1991, NIOSH sponsored a public meeting to address whether workplace protection factor (WPF) studies should be used for respirator certification. A representative of this manufacturer made a presentation stating *“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.”* 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. However, OSHA still relied on the non peer-reviewed WPF studies for assigning the protection factor for the filtering facepiece.

The elastomeric half-mask respirator provides a better face seal than filtering facepieces, since most elastomeric half-mask respirators are made of a 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. In contrast, the majority of filtering facepieces are made of less pliable fabric and come in only one or two sizes with non-adjustable head straps. Filtering facepieces with an adjustable nose piece band cannot obtain repeatable fit factors. They come in a variety of shapes, such as formed cup, flat, half fold, pleated, accordion folds, 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.

Dr. Kenneth Brown, the contractor who performed the statistical analysis of OSHA selected WPF 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. Chamber studies, or some other assessment methodology with experimental controls, are needed for a baseline test and comparison of respirators”* (Ex. 5-1, H-049C). OSHA ignored his recommendations.

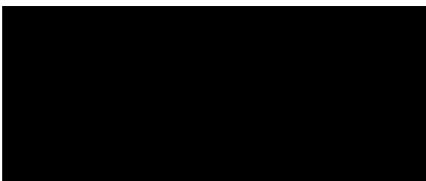
You stated in your April 15, 2005 letter that the final rule (APF) will be based on information that is on the record. However, OSHA entered information that does not meet the DOL Data Quality Act Guidelines into the APF docket. OSHA ignored the DOL requirements and selected non peer-reviewed studies for rulemaking. Also, the data selected by OSHA has failed to meet the objectives of utility, integrity, accuracy and reliability. OSHA has had eight months to comply with the DOL Data Quality Act Guidelines in developing the APF proposal but has purposely

of utility, integrity, accuracy and reliability. OSHA has had eight months to comply with the DOL Data Quality Act Guidelines in developing the APF proposal but has purposely ignored the guidelines established by the Labor Department. OSHA expects employers to comply with its safety and health regulations, but how can OSHA enforce these regulations if the Agency does not comply with DOL requirements?

I request that you reconsider my January 28, 2005 request on data correction for information used to develop the OSHA proposed standard on the Assigned Protection Factors (copy enclosed). If you are not able to grant my request, please provide me with reasons and on the procedure for requesting a higher level review of my request.

Please contact me if you have any questions. Thank you for your assistance.

Sincerely,



(Name removed)

Enclosures

References

1. Letter from Frank White, Acting Assistant Secretary for OSHA to Peter G. Nash, Counsel for 3M, September 5, 1986.
2. Letter from Patrick Tyson, Acting Assistant Secretary for OSHA to Peter G. Nash, Counsel for 3M, April 15, 1986.
3. U.S. Court of Appeals, District of Columbia Circuit. Nos. 78-2014, 86-1075 and 86-1157. 825 Federal Reporter, 2d Series, 482-494 (1987).