July 21, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
Cincinnati, OH 45226

Re: Proposed Rulemaking
42 CFR Part 84

Gentlemen:

Willson Safety Products has been in the business of supplying personal protective equipment to workers for over 120 years. During that time we have accumulated extensive experience with the certification procedures of the Bureau of Mines, and it's successor approval agency NIOSH. We are quite familiar with the problems inherent in the existing 30 CFR Part 11, and have been active in the various committees and groups working on the proposed revisions since the early 1980's.

Willson supports the intent to upgrade the existing regulation as long as it will provide the following results:

1. Significant improvements in the level of protection provided to respirator users.
2. Improve the ability of the user to distinguish what level of protection will be afforded with each respirator.
3. Classify filters on their ability to inhibit the penetration of particulates of the most penetrating size.

Willson does not agree that the proposed 42 CFR Part 84 accomplishes these goals at this time.

Our reasons are as follows:

1. The proposed testing methodology has not been proven to be repetitive, nor consistent at this time. Although certain strides have been made since the 1987 attempt to publish the revised standards, there still remains the inconsistencies noted in "round robin" testing, questions concerning the differences in results between hot and cold generated DOP, lack of performance data on "solid vs. liquid and solid" filters and the efficiency of electrostatic media as compared to mechanical filter media using the proposed test protocol. We see no point in replacing what everyone agrees are questionable current test methods (silica dust and lead fume) with newer test methods based on a not yet validated test protocol.
2. The proposed 42 CFR Part 84 does not make it easier for the end user to decide what level of protection they will be receiving. The proposed rulemaking eliminates the descriptive nomenclature the industry has been trained to implement, and essentially substitutes a ranking of efficiencies, that leaves the user the problem of determining “what does the respirator protect me against”? If this is where the rulemaking is intended to go, only issue approvals for filters against liquid and solids that are 99.97% efficient. This is the only way to provide the best protection for the end user. Of course, this will be a substantial cost burden for the end user.

3. The filtering efficiencies proposed are set at levels of 99.97, 99, and 95 percent efficiency. We would ask why? How do the existing respirator filters approved for over sixty years perform against the new standards? What is the current level of protection being afforded to the end user? What data has been generated and published substantiating the assumption these three levels of filtration efficiencies will actually improve the protection afforded to the end user. It’s nice to assume that a higher efficiency filter automatically provides improved protection, but we would question this assumption. We also question the assumption that higher protection is required in all cases. Where’s the correlation between the change in the standard and actual improvement in protection? Since we don’t know how the current non-HEPA respirators perform against the solids only test protocol, how can we go forward with a rulemaking that assumes benefits without backup data?

4. Willson does not support the addition of a solid only approval. While the contaminant hazard may be a solid particulate only, the efficiency of media such as electrostatic filters is impacted by liquids as benign as water vapor found in work environments such as asbestos removal, or many areas of the country which suffer from high humidity environments. We believe, given the current use of electrostatic media by Willson and other manufacturers, and possible use of electrostatic media under new standards that a solid only approval would be misleading and give users a false sense of security in many typical work environments.

There are other, less critical issues with the standard that also need to be resolved such as harmonization with international standards, tolerances of test flows, resistances, and time limits for approvals under 30 CFR Part 11 being valid in the marketplace.

Willson does support the intent to improve the current respirator certification procedure, and agrees that many aspects of the proposed 42 CFR Part 84 are an improvement over 30 CFR Part 11.

However, we request that the proposed rulemaking be delayed until the details that would provide an improved level of protection to respirator users are resolved.

Very truly yours,

WILLSON SAFETY PRODUCTS

James P. Kline,
Director of Operations

JPK/mk