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SAFETY PRODUCTS

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84-194

February 22, 1988

Dr. Nelson Leidel
Docket Officer
NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Dr. Leidel:

Willson Safety Products, a Division of WGM Safety Corp., appreciated the opportunity to observe the informal public hearing which took place in Washington on January 27 and 28, 1988.

Willson has several comments on specific areas addressed during the NIOSH testimony. Our comment on each issue is as follows:

1. The focus on "Mines" and "Mining"

The statement in the testimony "Industrial worksites could, therefore, be equally appropriate test sites for the required workplace testing", is contradictory to requirements in the proposed regulation.

The definition of "workplace", "simulated workplace" and "respirator" specifically reference only mines with no mention of industrial worksites. The only interpretation this leaves is that the regulation is for certification of only respirators worn in mines.

The preamble to the regulation requires that the "simulated workplace" be correlated with the "workplace testing". Since there are no workplace test protocols at this time, workplace testing does not exist, and thus, "simulated worplace" testing is also nonexistent. Therefore, NIOSH cannot say they are allowing the use of industrial worksites.

If the intent of NIOSH is to certify respirators for industrial use and to allow field tests in an industrial environment, then it must be stated as part of the regulation and not as a statement of clarification. The Administration Procedures Act requires that final rules be no more restrictive than the proposal. If NIOSH were to follow through with their intentions to certify industrial use respirators, they are first required to repropose the rule to reflect this intent. Not doing so would require an industrial use respirator to meet a standard promulagated for "respirators" which, by NIOSH definition, are "worn by an individual engaged in mining...".

2. Economic Impact of the Regulation

NIOSH should not have assumed that the impact of the regulation would not exceed $100 million based on the disc study questionnaire. The questionnaire was vague and entirely too confusing for a proper impact assessment. The manufacturers could not respond in an accurate manner without the knowledge of the proposal NIOSH intended. Also, NIOSH should not have made assumptions for the entire industry based on responses from only "some" manufacturers.

The statement made by NIOSH that "... these estimates [industries] are based on two critical, but incorrect, assumptions", is in itself erroneous. NIOSH says the industry was wrong in assuming that field testing must take place in mines. For the reasons stated previously, the regulation does, most definitely, require that this testing take place in mines. In addition, the manner in which these costs were calculated does not take the test site into consideration.

The second erroneous assumption made by NIOSH is that the industry calculated the field testing costs based on testing each exposure agent for which the respirator could be used. These costs were calculated by choosing a conservative number of substances. Three substances for each approval catagory, per respirator, was the number selected. The cost was not calculated based on every exposure agent. To test a respirator against all applicable chemicals is not feasible. New chemicals are developed constantly and it would be, at best, difficult for the field testing to keep pace with this development.

The bottom line is that a proper economic assessment cannot be made when the regulation is incomplete and lacks protocols. The proposal must be withdrawn until such time as it can be rewritten and properly proposed.

3."Self Certification Concerns"

Willson supports NIOSH performing all tests, on all manufacturers respirators, for which there are requirements in the regulation. If NIOSH has the "option" to validate tests as described in the testimony, the end result could be biased and inconsistent decisions on NIOSH's part. If NIOSH has reason to believe that a test is not necessary, then it should be removed from the regulations.

4. The "Workplace Testing Protocol"

The "Workplace Testing Protocol" should have been included in the proposal. The entire rule is meaningless without it. The proposed regulation should be withdrawn until such time as the protocols are complete and can be added to the proposal.

The flexibility in the workplace testing NIOSH plans to allow the manufacturers may lead to meaningless results. Tests which are performed in an inconsistent manner from manufacturer to manufacturer, offer the user no basis for comparison of those respirators. This could possibly result in less protection to the end user.

There should not be allowances for certification of respirators to a higher performance level relative to fit characteristics. This could result in marketing strategies which lead to unfair competition. NIOSH is assuming that by certifying a respirator to a higher protection factor it will be a better respirator. This is not necessarily true and could result in reduced worker production.

The statement referring to the manufacturers being able to appeal the rejection of a workplace study is unfounded. In the proposed regulation the appeals procedure results in a Judges' decision which is non-binding; in essence, the appeal does not exist.

5. "Organic Vapor Cartridges"

The cartridges and canisters on the market today will have to be larger to meet the proposed requirements with the same safety factor. With the current available technology this will mean heavier and bulkier sorbent elements. This can result in less protection if the respirator is not readily accepted by and therefore worn by, the worker.

Testing cartridges and canisters as described in the proposal will not simulate the effects of storage in high humidity environments. The equilibration to simulate use in high humidity environments may require changes which could result in more detrimental effects than is warranted by the increase in service life. NIOSH has attributed the need for this requirement to the concern that cartridges and canisters are used against substances having poor warning properties. This statement contradicts the regulation which prohibits this usage unless the respirator has an end-of-service-life indicator. In addition, NIOSH is not a regulatory agency which governs respirator use.

The statement made in the NIOSH testimony "...no similar comments have been made for any cartridge other than [for] organic - vapors " is incorrect. Willson did make the recommendation in our initial written comments to maintain the equilibration tests as in 30 CFR Part 11 for all cartridges and canisters.

It is unreasonable to implement increased performance requirements in order to "force" advancement in sorbent technology. Based on the technology available today, it is not possible to determine what advancements will take place in the next five years.

6. "Filter Technology"

Willson strongly supports the necessity of changes in the test methods for particulate filters. One of our major areas of concern over the changes in the proposal is, "How will the proper filters be selected when specific approvals no longer exist?" This information should have been made available by the applicable regulatory agencies at the time of proposed rulemaking.

It is not necessary for all filters to remove both liquid and oil mist contaminants. To the publics knowledge, there is no medical data or research to justify this requirement. Solid particulates are a more commonly encountered respiratory contaminant. Most oil mist contaminants require the use of a HEPA filter due to the PEL for those substances. Since the HEPA filter is available and does remove both types of contaminants, this requirement is unnecessary. If NIOSH has any data which does support this requirement, it must be published for public review.

Our position on 42 CFR 84 is as follows:

1. Willson supports the need to update 30 CFR Part 11. The proposed 42 CFR 84 does not, at this time, offer an improvement to the existing procedures.

2. Willson supports the continuation of NIOSH as the certifying agency for respiratory devices and does not support any concept of self - certification or third party certification at this time.

3. Willson recommends that the proposed 42 CFR 84 be retracted, rewritten, and resubmitted with the appropriate corrections and supporting back ground data included.

If there are any questions concerning our position on 42 CFR 84, please let us know.

Sincerely,

James P. Kline
Director of Operations

JPK/kmp