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**To:** NIOSH Docket Office  
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**From:** Jeffrey S. Birkner *JB*  
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Enclosed please find our comments on 42 CFR 84 which we would like entered into the public record.

JUL 22 1994

## INTRODUCTION

Moldex-Metric, Inc. is a major manufacturer of disposable dust/mist, dust/mist/fume respirators and twin cartridge half masks. We have been in this business for more than 15 years. We are actively involved in the development of ANSI standards, commented on previous NIOSH and OSHA proposals, participate in the American Industrial Hygiene Association respiratory committee, and serve on the Board of the International Society for Respiratory Protection. We are also members of the Industrial Safety Equipment Association.

We have accumulated a lot of expertise and knowledge in the field of respiratory protection and we support any reasonable government standards that improve worker health and safety. In this regard we have diverse research and development staff, in addition to well equipped laboratories, both in the U.S. and Europe, where Moldex has a manufacturing and marketing subsidiary.

We wish to submit our comments on the proposed 42 CFR 84 for the record. Our comments will cover all areas where we believe NIOSH should give further consideration prior to promulgating the final rule. We wish to point out that our comments on most points are not extensive as we are in substantial agreement with comments provided to the docket by the ISEA. Our comments regarding the cost impact of the proposed 42 CFR 84 are detailed as we have carefully analyzed the impact of this proposal in terms of costs to the manufacturer and ultimately the consumer. We are prepared to provide further details to NIOSH if they should require further information regarding our cost analysis.

Generally speaking we are in agreement with NIOSH's goal of an improved regulation that ultimately improves respiratory protection for American workers. To this end we commented in 1987 that we would like to see any new NIOSH respirator standard that is in alignment with the European CEN Standards. We wish to reiterate this concept for the following reasons:

1. Most U.S. respirator manufacturers must already comply with the CEN regulations in Europe, as most of these U.S. manufacturers market their products in Europe.
2. These CEN regulations go well beyond the performance requirements and protection levels that are currently required in the U.S. by NIOSH and OSHA.
3. The federal government encourages the use of international standards for regulatory applications. This is cited from OMB Circular A-119, 7a (2), October 20, 1993.
4. Costs to both users and manufacturers of the current proposal would be reduced, while users would have available products of greatly enhanced performance. The products are available now from

most major U.S. respirator manufacturers and at a reasonable cost increase over current NIOSH certified products.

5. The global economy extends to personal protective equipment. We view the testing and performance requirements of the proposed 42 CFR 84 as a step away from globalizing these types of standards, and would make harmonization of international respiratory standards more difficult. This would put the U.S. at an economic disadvantage with many of our trading partners.

#### **MODULAR APPROACH**

Although we understand why NIOSH has chosen the modular approach we feel that it is important to note that the overall economic impact of this regulation cannot be assessed without looking at the complete standard. Also, the use of a modular approach makes it extremely difficult for any manufacturer to begin developing any product without knowing what later modules may effect the final design of a product. We believe that the overall economic impact to the manufacturers will far exceed \$100 million.

#### **REFERENCE TO HEALTH CARE INDUSTRY**

While we agree that it is certainly within NIOSH's purview to promulgate a standard which also addresses the health care industry, especially exposure to TB, we are not sure that it is in the public's best interests that this be done in the same standard. Industrial use situations far exceed those of the health care use situations. Industrial respirators have completely different use situations from those used to protect against infectious agents. Industrial respirators are use against substances which have PEL's or TLV's and whose effects usually require repeated and long term exposure. Infectious agents, on the other hand, may require only a single exposure to the agent, do not have exposure limits, and do not load the filter. We therefore believe that these use situations should be addressed in different standards or at least to the extent that one test criteria not be required to meet both use situations.

#### **GRANDFATHERING**

We are of the opinion that upon issuance of the final standard that it should become effective immediately with the following provisions:

1. NIOSH accept new applications to 30 CFR 11 for a period of six months after 42 CFR has been issued.

2. NIOSH allow extensions of existing approvals to 30 CFR 11 for a period of two years for any substantial changes that may affect filter performance  
e.g. filter media supplier, media weight.
3. NIOSH allow extensions of existing approvals to 30 CFR 11 for a period of four years for any non-substantial changes to the respirator, e.g. color change, strap materials.
4. NIOSH allow the sale and distribution by manufacturers of respirators that have been certified under 30 CFR 11 for a period of four years.
5. NIOSH allow the use of respirators no longer in the control of manufacturers that have been certified to 30 CFR 11 for an unlimited period of time.

#### SOLID AND LIQUID/SOLID CLASSIFICATIONS

Although we agree that classifying the two use situations certainly provides greater flexibility in terms of realistic use situations for the end users, we feel that these classifications are probably not specific enough and may be misleading to the enduser. A solid certification should allow that such a filter be used for all types of solid particulates and most water based liquids, as is the practice in Europe. A liquid/solid certification should allow that such a filter be used for all other non-water based liquids. Additionally, we are concerned that the use of DOP as the test agent for the liquid/solid certification does not accurately reflect the majority of non-water based liquids encountered in industry. We suggest that NIOSH look at some alternatives, such as paraffin oil.

#### FILTER EFFICIENCIES

The filter efficiencies proposed by NIOSH should be modified in two of the classes. We agree that Type A filters should have an efficiency of 99.97%. We believe, though, that type B should have an efficiency of 96% rather than 99%, and that Type C should have an efficiency of 90% instead of the proposed 95%. Type B should be changed to 96% because 99% is so close to 99.97% that from a production, as well as, use standpoint there will be very little difference between Type A and B. This will result in a very minor cost differential between the two types (on the high side) and will not provide any substantial differences in the protection provided. Obviously, the point of having various classes of filters is to provide protection which is commensurate with the need, as well as, cost. Type C should be changed to 90% efficiency as this will provide protection for the relatively less toxic substances at a reasonable cost.

## **INHALATION AND EXHALATION RESISTANCES**

All filters tend to have two competing characteristics, that of resistance versus efficiency. As filters are made to be more efficient their resistance also goes up. The resistance requirements in 42 CFR 84 are the same as those from 30 CFR 11, yet the filter efficiency requirements are much more stringent. Design restrictions inherent in these filters (that they must be designed to fit on a facepiece) and the fact that the only way to lower the resistance and keep the efficiencies the same may be to increase the surface area of these filters. This may result in pleated filters for all classes of filters. Not only may this be technically infeasible for some of these filters, but would increase the cost of the filters substantially with little benefit to the user. We therefore recommend that NIOSH change the initial inhalation resistance from 30 to 35mm H<sub>2</sub>O, and the initial exhalation resistance from 20 to 25mm H<sub>2</sub>O. This will allow the manufacturers some latitude to develop filters at a reasonable cost without compromising safety or comfort to the user.

## **FILTER LOADING CHARACTERISTICS**

NIOSH is requiring that all filters tested must contact their respective challenge aerosol to 200mg. We believe that this is derived from 30 CFR 11 which reflected a realistic filter load in a work environment at the time these tests were developed. Nowadays, it would be almost inconceivable that any work environment would have such high exposure levels. We believe that 50mg would be more appropriate. A filter, especially a disposable filtering facepiece, used for 8 hours would have to be exposed to 6.25mg/hr of contaminant in order for it to contact 50 mg of contaminant. We feel that although even this is a concentration that is not typically seen in the work environment, it is certainly more realistic than 25mg/hr which is what 200mg contact would equate to over an 8 hour period.

## **FIT TEST REQUIREMENTS**

NIOSH is requiring that all particulate respirators be fit tested using Isoamyl Acetate (IAA). It is our belief that it is not necessary for NIOSH to require fit testing since OSHA requires this of every respirator wearer in every work situation once a year, as a minimum. Fit testing by NIOSH using a panel does not in any way reflect how well a facepiece fits on a particular individual in the field. Proper fit can only be ensured by fit testing each respective user. If NIOSH insists on conducting a fit test we would recommend some method other than IAA. IAA is a vapor. This would therefore require that the manufacturer design a surrogate respirator just for the fit test. Creating such a surrogate to comply with this test would undoubtedly change the respirators fit

and breathing characteristics. We suggest that it would be more reasonable to fit test a particulate respirator with a particulate challenge such as saccharin, bitrex, or a large particle quantitative fit test.

#### **STATISTICS**

In 1987 NIOSH required that the manufacturer ensure that respirators achieve a 95% confidence limit for 90% of the population of respirators manufactured. NIOSH has since raised this to 95% confidence limit for 95% of the population of respirators manufactured. This increase in the overall confidence limit will result in a much greater cost to the user with little discernable benefit. We suggest that NIOSH return to their 1987 proposal. We also suggest that NIOSH allow any manufacturer to forego such statistics if they do 100% filter screening to ensure that all filters for sale will comply with the filter efficiency requirements as a minimum.

## COST IMPACT FOR DISPOSABLE PARTICULATE RESPIRATORS

Following our presentation at the NIOSH Hearing we have further evaluated the cost comparison of current 30 CFR 11 products versus the proposed 42 CFR 84 products.

Although at this stage of rulemaking all details are not complete or finalized, we have made certain assumptions and estimated costs based on the proposal as written and our evaluation of current commercially available filter media. The following comparison is for products manufactured by Moldex only, and in no way represents the cost of other brands. The information used to reach these figures is proprietary and confidential but should NIOSH request further details then Moldex would be willing to enter into a limited general discussion.

### COST COMPARISON FOR DISPOSABLES

#### 30 CFR 11

User Price <sup>1</sup>

#### 42 CFR 84

Estimated User Price <sup>1,2</sup>

		Solid	Liquid/Solid
Dust/Mist	\$0.68	C \$6.35	\$10.97
Dust/Fume/Mist	\$3.89	B \$6.61	\$11.13
HEPA <sup>3</sup>		A \$6.77	<sup>4</sup>

- Notes:
- 1.- Based on 40% markup from lowest Distributor Cost.
  - 2.- Includes cost of elastomeric facepiece necessitated by proposed Banana Oil fit test requirement and increased surface area required to meet efficiency/resistance requirements.
  - 3.- Not manufactured by Moldex.
  - 4.- No commercially available filter media currently would meet the requirements for a disposable type filtering facepiece.
  - 5.- Statistical requirements under 42 CFR 84 indicate that costs could be increased further.

Our analysis shows that the average cost of respirators would increase between 9.3 to 16.1 times the current user price for Dust/Mist to Type C under proposed 42 CFR 84. Similarly the cost of Dust/Fume/Mist would increase by 1.7 to 2.9 times for Type B.

If NIOSH's estimate of 110 million disposable respirators per year are used, then the cost impact of 42 CFR 84 module 1 would far exceed \$100 million.

We strongly urge NIOSH to reevaluate the overall cost impact of the entire 42 CFR 84 proposal ( all module).