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Moldex-Metric, Inc. is a major manufacturer of disposable dust/mist/fume, particulate, respirators and twin cartridge half masks. We have been in this business for more than 15 years. We have been actively involved in the development of ANSI standards, commented on previous NIOSH and OSHA proposals, participated in the American Industrial Hygiene Association respiratory committee, and serve on the Board of the International Society of 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 have requested time today to comment on the proposed 42 CFR part 84, Supplementary Information section V (26859), to illustrate to those present and for the record the potential economic impact that this proposed standard will have on U.S. industry and workers currently using NIOSH certified disposable particulate respirators.

These are by far the most popular and widely used particulate respirators. NIOSH has estimated that employers annually purchase over 110 million, and this proposal will have, by far, the most impact on these products and the workers who use them.

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 a new NIOSH respirator standard that is in alignment with the European CEN Standards. We take this opportunity to reiterate this concept for the following reasons:

1. Why reinvent the wheel? Many of the same U.S. respirator manufacturers and industries have already been living with CEN regulations in Europe that go well beyond the performance and protection levels that are currently regulated here by NIOSH and OSHA.

2. Let us rise beyond the "Not invented here" cliché and look to the OMB Circular #A-119, 7a (2), October 20, 1993, which states that international standards should be considered in regulatory applications....etc.

3. Costs to both users and manufacturers of the current proposal would be reduced, while users would have available products of greatly enhanced performance. These products are available now from most major U.S. respirator manufacturers and at a reasonable cost increase over current NIOSH certified products.

4. The global economy may soon extend to respiratory protection. We see the testing and performance requirements of the proposed 42 CFR 84 as a step away from globalizing these types of standards, and they would actually make harmonization of international respiratory standards more difficult. We ask NIOSH to examine this proposal to see if it is in line with the spirit of OMB circular A-119 and take the comments of NIOSH staff who are currently assigned to work on international harmonization.

Beyond this, we feel that with this proposal NIOSH is attempting to make up for lost time and so the pendulum has swung too far the other way. No one would disagree that 30 CFR 11, now more than 20 years old, needs revision. And yet it resulted in respiratory products which, if used properly and for the appropriate use conditions, perform quite well; as evidenced by many workplace protection factor studies. 42 CFR 84, as proposed, has swung past the CEN Standards in terms of stringency and will result in a cost to industry of many times what is now spent on respirators that are currently certified under 30 CFR 11.

We have carefully studied this proposal and the testing, equipment, and performance requirements with particular regard to disposable particulate respirators.

Firstly, we have examined and tested every commercially available filter media, and we have not found any available that would meet the requirements of all three types (A,B,C) in both the Solid and Liquid/ Solid categories at a reasonable cost. The only media that would meet certification requirements of a limited number of the new types is currently made in the United Kingdom at a cost to U.S. respirator manufacturers that is at least 20 times the media used to meet current standards for disposables.

For example:

Cost of commercially available filter media to meet 30 CFR 11 disposable dust/mist requirements is between 60 cents - \$1 per square yard.

Cost of European commercially available filter media to meet proposed 42 CFR ~~84~~ requirements is between \$12 - \$17 per square yard, depending on the type (A,B,C) and whether it is for Solids or Liquids/Solids.

Secondly, the fit test requirements of Section 84.181 would necessitate elastomeric inner flanges to be added to all certified disposable respirators in all categories.

We have attempted to project the average user cost of disposables designed to meet 42 CFR 84 and make a cost comparison with current 30 CFR 11 approved products. Our best efforts follow:  
30 CFR 11: NIOSH estimates 110 million disposable respirators.  
Average current user cost \$1 each (NIOSH estimates \$1 - \$8 each)

42 CFR 84: Moldex projected average user cost (with enhanced European media and inner flange) \$5 - \$10.

Projected increased user cost for disposables of 42 CFR 84: \$440 million - \$990 million.

Moldex strongly believes that the total cost impact to U.S. industry of the currently proposed 42 CFR 84 will be well beyond \$100 million. We suggest OMB/NIOSH need to investigate and take into account the following factors for all types of respirators, in addition to the figures above:

- 1) The cost of upgraded filters, including the substitution of stacked chemical/pleated fiberglass (HEPA type) cartridges in place of currently used single ply prefilters for all applications such as Paint Spray/Pesticide. This is applicable to twin cartridge, elastomeric half mask, respirators.
- 2) The possibility that inexpensive, widely used and worker accepted disposable particulate respirators would be replaced by costly reusable elastomeric cartridge masks.
- 3) The increase cost of respirator maintenance and training programs that are associated with reusable respirators.
- 4) The training and education programs needed to explain the new regulations to the user public. This will have to be extensive in order to minimize confusion, misuse and therefore limit liability.
- 5) The statistical (Standard Deviation) requirements of the current proposal might necessitate much higher waste costs to the respirator manufacturers (see ISEA comments), that will have to be passed on to users via higher prices.
- 6) The cost of Liquid/Solid filters are considerably higher than Solid filters due to the extremely degrading affects on filter efficiency of the loaded DOP challenge.

If users upgrade to L/S filters by a high percentage, because of Liability/Worker Compensation considerations, NIOSH user guidelines, or market pressures, then costs to Industry would be significantly higher.

The question that comes obviously to mind is:

Will the magnitude of the potential cost increase have a commensurate increase in improved worker safety and health?  
We do not believe so.

We want to see an upgrade in the regulations, but not to the extent that the cost might result in decreased health because employers might decide that they cannot afford to provide adequate and appropriate protection. NIOSH has an opportunity now to increase worker protection, for a modest cost increase to U.S. industry, by taking a more reasonable and international view of testing, equipment, and performance requirements.

Thank you.

MOLDEX-METRIC, INC.

Bernard Mishkin, Vice-President  
for Jeffrey Birkner, CIH, Technical Service Manager.

**•Moldex-Metric Inc.**

Manufacturer of NIOSH-certified disposable dust/mist/fume respirators and chemical cartridge half-masks.

## **Moldex-Metric Inc.**

Presentation on supplementary Section V (26859) -- potential economic impact of proposed 42 CFR Part 84 on U.S. industry and workers currently using NIOSH-certified disposable particulate respirators.

## Disposable particulate respirators

- most popular and widely used respirators
- NIOSH estimates over 110 million are purchased annually
- new proposal will have the most impact on disposables

## European CEN Standards

- Go beyond current 30 CFR 11
- OMB #A-119, 7a(2)
- Products available now at a reasonable cost increase
- Globalize respirator standards

30 CFR 11 needs revision but is 42 CFR 84, as proposed, too costly?

Commercially available filter media for disposables to meet A,B,C, in both S and S/L is not available at a reasonable cost

Example:

30 CFR 11 Dust/Mist filter media -- \$0.60 - \$1.00 per sq. yd.  
42 CFR 84 filter media \$12.00 - \$17.00 per sq. yd.

Fit test requirements of 84.181 would necessitate elastomeric inner flanges  
at extra cost

Estimated average user cost of disposables:

30 CFR 11 -- \$1 each

42 CFR 84 -- \$5-\$10 each

110 million purchased annually

Projected increased user cost \$440 million - \$990 million

OMB/NIOSH need to investigate further:

1. Cost of upgraded filters, including stacked chemical/pleated fiberglass (HEPA) and the influence of users guide for specific applications.
2. Would costly cartridge masks replace inexpensive disposables?
3. Cost of respirator maintenance and training programs associated with reusables.
4. Cost of training and education programs to explain new regulations to the user public.
5. Statistical requirements might necessitate higher waste costs, and therefore higher prices.
6. The higher cost of upgrading to Liquid/Solid filters from current filters, including Paint Spray/Pesticide Prefilters.

It is possible for NIOSH to upgrade the regulations for a more modest cost increase to U.S. industry by taking a reasonable and international view of testing and performance requirements.