

July 21, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
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Cincinnati, Ohio 45226

This letter is response to 42 CFR Part 84, Respiratory Protective Devices; Proposed Rule, published Tuesday, May 24, 1994.

The focus of these comments is the impact of the proposed rule on the healthcare industry. Since this rule will be used to certify respirators used in the prevention of tuberculosis transmission, we feel that some guidelines specific to that use are justified and should be incorporated in the final rule.

We feel that the rule as proposed is a significant advance from previous standards, but that the rule does not incorporate testing methodologies or standards that are most conducive to the development of an effective prevention of the spread of tuberculosis. To wit:

- Particle sizes for the test aerosols (0.06 to 0.11 μ m for NaCl) are much smaller than the infectious agent of tuberculosis, *Mycobacterium tuberculosis* (1 to 5 μ m).

- A flow rate of 85 liters per minute, while representative of respiratory rates during heavy labor, does not represent the respiratory rate of health care workers. We feel a rate of 50 lpm would be more realistic.

- A differential pressure of 30 mm of water is very high. This high limit, needed to accommodate the higher resistance of filters that meet the filtration requirements, indicates that the standards will impose a greater burden of discomfort and a higher risk of acidosis in healthcare workers using respirators without negative pressure valves such as those currently used in their industry. This high differential pressure also increases the chance that respirators will leak, or that their use will be avoided, or that the respirators will be used improperly.

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The imposition of standards which are beyond what is actually required, as noted above, is counterproductive to the mission for which those standards are being imposed. We feel that a separate classification for the healthcare industry would be an excellent refinement of this rule, in that it would minimize cost and speed the development of respirators which would protect the user from this threat. We feel that the nature of the tuberculosis hazard and that the context of the respirator use in healthcare settings are sufficient to warrant a specific standard within the rule which specifically addresses this issue.

The issues addressed above, as well as several others, were mentioned by TecnoI in our comments at the Public Meeting in Washington, D.C. on June 23 & 24. We have enclosed a transcript of those comments for reference.

Part II of this document contains excerpts from comments submitted by the Industrial Safety Equipment Association. We present these excerpts as the clearest possible means to express our support.

TecnoI appreciates the opportunity to participate in this process, and we hope that these comments have been constructive and conducive to the development of standards which will protect respirator users in the most efficient, affordable, and expeditious manner possible.

Sincerely,



Joe Rummler
Manager for Testing and Technical Support
TecnoI Medical Products, Inc.

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PART II

Tecnol would like to express support of the following comments made by the Industrial Safety Equipment Association. This support is voiced exclusively for those comments quoted below.

"A. Grandfathering Provisions

- ii. Two years after publication of 42 CFR 84 as final, manufacturers may no longer sell or distribute respirators certified to the criteria of 30 CFR 11 as NIOSH-approved or NIOSH-certified respirators.
 - ISEA recommends that manufacturers be permitted to sell and ship products certified to the 30 CFR 11 criteria as NIOSH-approved or NIOSH-certified respirators for four years after the date of publication of the final rule.
- iii. Two years after publication of 42 CFR 84 as final, manufacturers may no longer sell or distribute respirators certified to the criteria of 30 CFR 11 as NIOSH-approved or NIOSH-certified respirators.
 - ISEA recommends that NIOSH limit application of the grandfather period to respirators that remain under the manufacturers' control.
- iv. The proposed rule does not address extensions of existing product approvals involving changes in filter media or filter specifications that affect filter performance.
 - ISEA recommends that for changes to filter media or filter specifications that would affect filter performance, submittals for extensions of existing product approvals be accepted for two years after the rule becomes final.
- v. The proposed rule does not address extensions of existing product approvals involving non-substantial changes to respirators that do not affect filter performance.
 - ISEA recommends that for manufacturer's making non-substantial changes to respirators that do not affect filter performance, extensions should be granted for existing product approvals for four years after the rule becomes final."

"E. Test Statistics

- ii. The proposed K factor of 2.22 is too high.
 - ISEA recommends that the K factor be changed to 1.778.

- A K factor of 1.778 is the equivalent of what would have been proposed for 30 samples under the 1987 proposal, and would prevent the costs of particulate filters from rising significantly while the relative protection afforded remain the same."

"F. Fit Testing

- i. The proposed rule requires that all particulate respirators be fit tested.
 - ISEA recommends that fit testing not be included as part of the certification program.
 - Fit testing during certification will create a false sense of confidence in the wearer and may discourage fit testing in the field.
- ii. The proposed rule requires that all particulate respirators be fit tested with isoamyl acetate, an organic vapor; to do so would require that the particulate filtering element be replaced with an activated carbon element.
 - ISEA recommends that NIOSH adopt either the Bitrex qualitative fit test aerosol using the protocol for saccharin in the OSHA lead standard or use a large particle quantitative fit test.
 - In many cases, changing the particulate filter to one that removes organic vapor would result in the creation of a surrogate respirator with different fit characteristics from the respirator seeking certification."

**TECNOL'S COMMENTS TO NIOSH ON
42 CFR PART 84
RESPIRATORY PROTECTIVE DEVICES; PROPOSED RULE, MAY 24, 1994
PUBLIC MEETING JUNE 23-24, 1994
WASHINGTON, D.C.**

Tecnol supports the strides forward that the NIOSH proposed ruling represents for the healthcare industry. We support the six classifications, that include solid and liquid solid classification.

We also express support of the comments presented by APIC, the Greater New York Hospital Association, the Society for HealthCare Epidemiology of America and the Health Care Association of New York.

However, we feel that there are several criteria in the proposed rule which may unnecessarily impede the development and proper use of respirators in the prevention of tuberculosis transmission.

These criteria are:

- Fit Testing
- Particle size and the nature of the particle used
- Flow rate and breathability

Section 84.181 describes a fit test method for non-powered particulate respirators which is not applicable to disposable respirators. These respirators have no inhalation ports which would allow the attachment of a charcoal filter. In order to eliminate transmission of isoamyl acetate through the filter media, the entire surface of the mask would have to be altered in such a manner that any testing for leaks would then be conducted under unrealistic fit conditions.

We request consideration of an alternate method, the qualitative saccharine fit test or the same test using Bitrex. This method does not involve alteration of the mask, a requirement which we feel is essential to realistically test the fit characteristics of the surgical mask style particulate respirator. Furthermore, this test is already in common usage in the healthcare industry.

Particle sizes below $1\mu\text{m}$ are not challenges representative of TB bacteria.

The problems mentioned yesterday (6/23/94) with aerosol generation, variability of performance with DOP and NaCl, suggest that alternate methods such as those using latex spheres of known size might be more easily performed and controlled. We also request clarification of what constitutes an acceptable alternative to DOP.

We feel that a flow rate of 85 LPM does not represent respirator rates achieved in a healthcare setting, and we suggest consideration of a more realistic, end use specific flow rate.

High differential pressure limits in the proposal, designed to allow for the higher filtration filters, do not take into account the construction of disposable respirators which have additional layers in their final configuration which would add to the differential pressure and decrease the actual breathability relative to the breathability of masks using filters isolated in valves, rather than incorporated into the entire surface area of the mask.

The result of these standards will be a disposable respirator which is significantly less comfortable than devices previously used in the healthcare industry, with the exception of HEPA filters, without a documented increase in protection against tuberculosis.

As with the HEPA, our concern on this point is that some healthcare workers (faced with only a possibility of exposure rather than a certainty) may intentionally fit the mask improperly during routine use, allowing unfiltered air to pass under the chin or around the sides of the mask, or they may rush through procedures which require the use of respirators causing unsafe conditions.

To summarize, we would like to request consideration of standards for respirators more suitable for use in the healthcare industry, so that the needs of that industry can be efficiently met without compromising the standards required in other industries.

Specifically, this standard could include a lower flow rate, such as 50 lpm, and a particle size of $1\mu\text{m}$, and a fit test applicable to disposable respirators, such as the saccharine qualitative fit test.

We feel that this would allow the development of highly effective and affordable devices to protect healthcare workers from tuberculosis and other airborne bacterial hazards.