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NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

42 CFR 84 Comments on Proposed Rulemaking

Dear NIOSH:

I am pleased that NIOSH is proceeding with issuance of this proposed rule updating certification requirements for respiratory protective devices (Federal Register Vol. 59, No. 99, Tuesday, May 24, 1994). The update of these criteria is long overdue.

I am concerned, however, that NIOSH, in expediting this proposed rule to provide less expensive respirators for protection against Tuberculosis in the health-care industries, may be compromising it's stated goals:

- To produce significant improvements in the level of protection provided to wearers of respirators;
- To enable users to easily discern the level of protection that can be expected when using a respirator; and
- To enable classification of filters on their ability to inhibit the penetration of particulates of the most penetrating size.

Specifically, I believe:

- 1) **The six particulate respirator classification system proposed by NIOSH appears less stringent, confusing and could result misuse and increased exposure:**

As proposed, the new classification system includes:

Type A/S	99.97%	Solid particulate only
Type A/L&S	99.97%	Liquid and Solid particulate
Type B/S	99%	Solid particulate only

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Type B/L&S	99%	Liquid and Solid particulate
Type C/S	95%	Solid Particulate only
Type C/L&S	95%	Liquid and Solid particulate

I believe that all particulate categories should be tested and certified against both liquid and solid challenge atmospheres. This would ensure that the respirator user is afforded the maximum protection.

As the "Solid Only" category products would be markedly less expensive, this may provide an incentive for employers to select the more economical product. Further, it is not reasonable to assume that respirator users will know when they are being exposed to liquid rather than solid particulate atmospheres. There are no warning properties and the contaminants may or may not present a visible difference. This presents a likely scenario for misuse and exposure, whether based on economic incentives, ignorance or accident.

What criteria or air monitoring/sampling methodology would be utilized to provide the industrial hygienist will data to differentiate "Solid" from "Liquid" particulate? It seems that the increased quantity of air sampling required to justify a particular respirator selection could negate the cost benefit of respirators and cartridges that were initially more economical. Without such data, it is likely that the most economical or the most protective selection will be made. In addition, many individuals who are not industrial hygienists are involved in respiratory selection. Without appropriate education, training and experience, the selection may be made based on price alone without understanding the differences.

Further, the Type A, B, C classifications add confusion as OSHA/NIOSH/EPA already use these terms for other respirators and personal protective equipment:

- Level A - Hazardous waste term specifying supplied air and gas-tight suit
- Level B - Hazardous waste term specifying supplied air and non-gas tight suit
- Level C - Hazardous waste term specifying air-purifying respirator and other PPE
- Level D - Hazardous waste term specifying no respirator. Other PPE as needed.

- Type A Supplied Air Respirator - NIOSH Term
- Type AE Supplied Air Respirator - NIOSH Term
- Type B Supplied Air Respirator - NIOSH Term
- Type BE Supplied Air Respirator - NIOSH Term
- Type C Supplied Air Respirator - NIOSH Term
- Type CE Supplied Air Respirator - NIOSH Term

Therefore, to avoid misuse and misapplication, I believe that all particulate categories should be tested and certified against both liquid and solid challenge atmospheres.

- 2) **The use of polydispersed and neutralized cold-nebulized DOP (cold DOP) challenge aerosol instead of the industry standard of monodispersed, thermally generated DOP (hot DOP) is less stringent:**

NIOSH has indicated that their intent is to test with the most penetrating challenge aerosols. I agree with this because workers can potentially be exposed to many different types of aerosols. If this is the intent, why has NIOSH proposed the use of cold DOP instead of hot DOP which has been the industry standard for classifying HEPA filters for many years? I have not seen published studies which now show that cold DOP is more penetrating than hot DOP? Has NIOSH conducted such studies? If so, this data should be made available. If not, the basis for using an alternative to the industry standard does not seem justified and could result in respiratory protection that is less protective instead of more protective.

- 3) **The need of the health-care industries for low-cost protection against Tuberculosis should not compromise the protection afforded other respirator users. OSHA should issue a separate standard for Tuberculosis in the health-care industries:**

It is my understanding that NIOSH is considering allowing the least protective proposed respirator classification (Type C/S, 95%) for protection against Tuberculosis and that NIOSH is creating this classification of low cost respirators to meet the needs of the health-care industries.

If a primary route of exposure to Tuberculosis is through airborne aerosols or particulates from the saliva of infected persons, I do not understand how a "Solid Only" respirator can afford adequate protection. Isn't saliva initially a liquid and after time, the liquid evaporates and a dry particulate remains? Clearly, liquid droplets are larger in size than the dry particulate resulting from airborne saliva and may be filtered by a respirator that provides lower removal efficiencies than 99.97% liquid and solid (HEPA). But what about the dry particulate that remains after the liquid evaporates? Do we know enough about the size of these Tuberculosis bacilli? Do we really know if a Type C/S respirator will adequately remove the contaminants? Do we really know the threshold concentration of airborne Tuberculosis below which does not cause infection?

It is clear that the Type C/S respirators would be less expensive but is there enough technical data to ensure that they would provide adequate protection against TB? In addition, it seems that appropriate protection based on technical data rather than cost should be the driving factor. Special provisions are not made for General Industry and Construction to provide less expensive respirators, particularly if protection may be compromised. I do not advocate a reduction in price when there is a question of protection, especially at risk of those in other

non-health-care industries who may opt for the inexpensive respirator without thoroughly understanding the differences in the six proposed respirator categories.

If the needs of the health-care industries are so different, I believe OSHA should address them in a separate Tuberculosis standard. The needs of the health-care industries should not reduce the standards established for other situations.

I hope that NIOSH will take these concerns into consideration prior to issuance of the final rule.

If you have any questions or require additional information, please feel free to contact me.

Sincerely,

A handwritten signature in blue ink that reads "Tamara A. Renkoski". The signature is written in a cursive style with a large initial 'T' and 'R'.

Tamara Ann Renkoski, IHIT
Managing Partner

enclosure