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DEPARTMENT OF HEALTH

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Diane Manning
NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C-34
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Ms. Manning:

On behalf of the New York State Department of Health (NYSDOH), we are writing in response to NIOSH's request for comments regarding the proposed revisions to the NIOSH Respirator Certification Requirements.

As NIOSH is well aware, respirators have been a particularly contentious issue with respect to tuberculosis control. While NYSDOH recognizes that this policy initiative is intended to have broad impact on the use of particulate respirators for all hazards, not just tuberculosis, the Department is hopeful that the new initiative will be an important step forward in resolving the tuberculosis respirator debate.

Overall, we believe this policy initiative is strong. Several aspects are noteworthy. The modular approach is sensible and will enable NIOSH to move through comprehensive reform in an organized manner. We also agree that the proposed testing requirements for particulate filters will significantly improve NIOSH's ability to evaluate respirator filters. In particular, testing respirators in the unloaded state and challenging filters with the most penetrating particles is likely to improve the certification process.

However, we have some serious concerns with respect to the proposal. First, we are concerned about the impact of these requirements on respirator fit, particularly as it pertains to disposable particulate masks. As we interpret your proposal and project forward, the new process is likely to result in certification of a number of dust-mist and dust-mist-fume respirators in the Type C category (filter efficiency of 95%), thereby meeting primary performance criteria as set forth in the CDC proposed revision of Guidelines for Preventing Transmission of Tuberculosis in Health-Care Facilities, which was published in the Federal Register dated October 12, 1993. As NIOSH indicates, this would result in a broader range of respirators available, and although not discussed, at a lower cost for tuberculosis control.

The Department views this as a positive outcome, but believes your certification proposal falls short by not factoring in or combining requirements for respirator fit, particularly for disposable respirators where the filter and the mask are one and the same.

Two issues stand out. First, if you compare the respirator structure of most disposable dust-mist(DM), dust-mist-fume(DMF) and HEPA masks, one can see that fit generally runs on a continuum with DM respirators designed with the least structural components to guarantee fit and HEPA respirators designed with the most in order to minimize leakage. Face seal leakage is a central concern with respect to respiratory protection. In the case of tuberculosis, our TB control guidelines stress the importance of education and respirator fit testing in order to guarantee the greatest level of confidence that workers have been provided with the brand of respirator best suited to their particular face. We have also known that the weakness of disposable masks are their inability to be reliably fit checked upon each use.

We believe that the issue of fit can be best addressed in two ways. First, in the certification process itself, respirator fit requirements should be incorporated into the test protocols, with disposable and reusable masks being subjected to at least equivalent challenge testing. As we noted above, we are particularly concerned about disposable respirators since fit tends to be more variable and the proposed certification process is likely to result in approval of a wide range of respirators with varying structural design which impacts on the degree of face seal leakage. Secondly, NIOSH should combine the new filter certification process with a requirement that manufacturers design all masks -- disposable or reusable -- in a manner that can be reliably fit checked upon each use. While many manufacturers claim their masks can be fit checked, to our knowledge, there are currently only two disposable masks on the market that have been designed to accommodate fit checking. While the designs need to be perfected, it is clear that the technology is there to accommodate this requirement. We believe NIOSH is in a unique position to move respirator technology forward through this revised certification process. The next step is for respirator manufactures to design affordable masks that are more comfortable, which do not interfere as seriously with communication and vision, but still provide adequate protection.

Finally, we believe that several issues need to be clarified with respect to the NIOSH proposal in order to adequately comment on the document.

(1) NIOSH states that the proposed certification requirements were not developed to specifically certify respirators against biological agents. While this might be a reasonable decision, no explanation is given on how your scientist came to that decision. Presumably studies have been done to show that airborne biological agents behave in a similar manner to other agents and distinctions in respirator design are not required. However, this point is deserving of more explanation.

(2) Both CDC and NIOSH are relying on the 95% efficiency as a baseline requirement. Again, what was the thinking which lead to this threshold figure.

(3) Issues related to projected implementation were only addressed in a more narrow sense in the certification proposal. In order to understand the future impact of the proposal and comment in an effective manner, the following needs to be explained. How will this new certification process impact on NIOSH's current respirator recommendations and mandatory requirements by OSHA? For example, current respirator requirements for lead and asbestos call for HEPA filtered respirators. Will documents be revised indicating the category of mask recommended for different exposures? How will the revised certification process impact on mandatory requirements by OSHA?

(4) The modular process is particularly accommodating for priority setting. How will constituent groups have input into the NIOSH priority setting process?

In closing, we would like to restate our general support for the new certification proposal.

Sincerely,

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