Dragon, Karen E. (CDC/NIOSH/EID)

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To: NIOSH Docket Office (CDC)
Subject: docket # NIOSH-036

Attachments: 1018610141-Proposal to reduce the cost and logistical negatives to the proposed TIL testing.doc

Proposal to reduce the cost an...

Please find attached some thoughts on the proposed TIL test requirement for respirators.

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Proposal to reduce the cost and logistical negatives to the proposed TIL testing.

Premise:
1. By eliminating excess testing on the best performing respirators the cost can be reduced.
2. By allowing testing outside NIOSH's physical location logistical problems can be reduced.

An observation:
In many industrial environments primary eye protection is required. The percentage increases when respiratory protection is required. The ability to wear prescription eye protection (which must be positioned correctly) may require tighter sizing in the nose area and thus a possibility of more sizes. The standard as proposed penalizes the development of respirators which take into account the full PPE package.

Proposals:
1. Set testing levels by a matrix of statistically equivalent eliminations of poor performing respirators. For example; 11/12, 17/20, 20/25 ... 26/35 (These combinations have not been statistically analyzed). Initial test would be 1 each from 1,2,3,5,6,8,9,10, 2 each from 4 & 7. Then 3 (more) from 4, 2 from 7. Then 1 more from 1,2,3,5,6,8,9,10 (for 25 subject panel).

This criteria rewards manufactures of better fitting respirators with lower testing costs. It is assumed that better (more universally) fitting respirators have higher development costs but they are advantageous to users because they have a higher probability of fitting properly if fit testing or donning are not done as diligently.

2. Allow targeted sizes to be tested at a lower level. It is probable that companies requesting these would have specific needs determined by the failures in their fit testing and therefore the ability to achieve a correct fit would be more closely monitored.

This would give manufacturers who want to take the risk of expanding the coverage to under represented populations less of a disincentive to do so.

** The presentations at the June 07 meeting indicated that improperly sized respirators were used in a portion of the tests. A further analysis of the data would allow determination of if the fit improved when size was factored in. If so this would support using less than the full panel for each size so long as the total for all sizes were a full panel. It could be argued that a respirator designed for a small face would almost allways fail on a large face and visa versa. If this analysis shows an improved result it would support allowing a respirator available in multiple sizes to use the accumulation of narrow panel tests to obtain the required 26/35 (or an adjusted ratio).

3. Allow companies to hire a NIOSH representative to travel to their test lab to monitor their pre-submission testing or their certification testing at satellite locations. So long as the test was monitored by NIOSH personnel the test would qualify as the certification test.

This would allow NIOSH to control acceptance of all tests performed outside their facility. As well as offering a manufacturer options to reduce their wait time and possibly their testing costs.

This would also benefit manufacturers of targeted sized respirators to utilize a local subset which may not be sufficiently available in the Pittsburg area.

4. Allow the manufacturer tests to be additive to NIOSH's tests so long as certain criteria are met. This may combine with the first proposal to obtain the 35 person sample but NIOSH's testing must meet the statistical guidelines previously outlined (item 1).

   This may not be workable. It is included as an additional way of looking at the total number of tests being done by the manufacturers.

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